SOUTH CAROLINA

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL BUREAU OF LABORATORIES

SERVICES GUIDE

C. EARL HUNTER COMMISSIONER

Arthur Wozniak, Dr.P.H. CHIEF, BUREAU OF LABORATORIES

TENTH EDITION 2006

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PURPOSE OF MANUAL

The purpose of this manual is to provide our clients with information about the laboratory services available and to provide a guide for collecting and submitting specimens for analysis.

This ninth edition can also be accessed on the DHEC Internet web site.

MISSION

The Bureau of Laboratories, S.C. Department of Health and Environmental Control, formerly named the State Public Health Laboratory, is a multi-disciplinary, integrated source of diagnostic services including analytical support and consultation for physicians, private laboratories and county health departments. The Bureau of Laboratories is prepared to assist in any national public health emergency.

The mission of the Bureau of Laboratories is to provide laboratory-based health and environmental assessments for accurate diagnosis, prevention and surveillance of infectious and chronic diseases, congenital disorders and environmental hazards to reduce the incidence of illness and death and to improve the quality of life among the people of the state.

BUREAU ADDRESS

The Bureau of Laboratories is located in the James A. Hayne Building at 8231 Parklane Road, Columbia, South Carolina 29223, on the campus of the State Park Health Center. State Park is located between Highway 555 (Farrow Road), Parklane Road and the I-77 connector (Bull Street extension or S.C. I-277) two miles north of I-20 and 2 miles west of Columbia Mall. Using the Parklane Road Entrance, the Hayne Building is at the end of the first left turn.

HOURS OF BUSINESS

The official working hours are from 8:00 A.M. to 4:30 P.M. Monday through Friday.

Weekend and Holiday Testing

The laboratory maintains an ON-CALL Roster for all weekends and holidays. Individuals requesting information or services of an emergency nature can call the main number, 803-896-0800. This number transfers to the answering service who will contact the Director on call.

Emergency Response/ Disaster Preparedness:

As part of the DHEC's Emergency Preparedness Plan of Action for emergencies, the Bureau of Laboratories is equipped and staff trained to respond rapidly and effectively to a medical emergency natural disaster or Act of Bioterrism. If the emergency occurs outside of regular working hours, personnel will be called back or work overtime as needed to provide laboratory support.

SPECIMEN RECEIVING

Specimens transported by General Services' courier are placed in specially marked boxes and are picked up by lab staff from the Sims-Aycock complex between 5:00 and 5:30 AM Tuesday through Saturday. Specimens are picked up by laboratory staff on weekends and holiday periods exceeding 24 hours from the U.S. Post Office and DHEC at 2600 Bull Street. These are sorted and stored according to established protocol to be accessioned on the next working day.

Specimens sent by first class mail are delivered from the Sims-Aycock complex by DHEC courier at 9:00 AM Monday through Friday. Those with a Parklane Road address are picked up by Material

Logistics' staff at 8:30 AM. The U.S. Post Office delivers at approximately 12:30 PM, Monday through Friday.

Specimens are accepted at the Hayne Building during business hours of 8:00 AM to 4:30 PM Monday through Friday, except for state holidays. Private couriers should call Specimen Logistics at 803-896-0898 to arrange for delivery at the back entrance of the Hayne Building. Private individuals delivering specimens must enter the building through the front entrance. The Protective Services Officer will assist them.

AFTER HOURS DELIVERY OF SPECIMENS

An after hours depository is located on the loading dock at the rear of the building. This depository is a refrigerator primarily for animal heads. If the specimen should not be refrigerated or may break if dropped into the depository, special arrangements for delivery must be made with the laboratory section conducting the test. This person will notify the Protective Services Officer on duty that a delivery is expected.

CONTACT PERSONS AND PHONE NUMBERS

(Area Code 803)

Reports		896-0897
Laboratory Request Forms/Mailing Containers		896-0913
Facilities Maintenance (Laboratory Instrument Service	es)	896-0919
Bureau Chief (Acting)	Arthur Wozniak, Dr.P.H	896-0801
Director, Diagnostic Microbiology Division	Jennifer Meredith, PhD	896-0965
Director, Analytical Chemistry Division	Thomas M. Hickey, PhD, DABCO	C896-0964
Director, Clinical Pathology Division	Marc S. Busnardo, M.D	896-0658
Director, Operations Division	Sarah J. Robinson, M.A	896-0941
Director, Facilities Management Division	David C. Rivers	896-0923
Director, Office of Quality AssuranceRobert	a Bartholdi, M.S. MT(ASCP)	896-3897
Director, Office of Laboratory Safety	Connie Gray, M.P.H	896-0956

LABORATORY ACCREDITATION AND CERTIFICATION

CLINICAL TESTING - CLIA ID # 42D0658606 INDUSTRIAL HYGIENE - AIHA # 100621 ENVIRONMENTAL LEAD - AIHA # 100621 DAIRY PRODUCTS - FDA # 45001

TESTING POLICIES

Persons Authorized To Order Tests

The Laboratory will accept clinical laboratory specimens for testing from physicians, health departments, and hospital laboratories, or as provided by South Carolina statues. These senders will be responsible for receiving, relating, interpreting, and/or distributing the data.

A clinical laboratory specimen is described as any material derived from the human body for the purpose of diagnosis, prevention, treatment or assessment for medical or legal purposes. Clinical laboratory specimens for drug-of-abuse testing from other sources (legal entities) will be accepted with prior approval of the appropriate Division Director or Bureau Chief. Inanimate substances and other samples submitted for examination (e.g., food samples, animal heads for rabies, veterinary specimens, etc) may be accepted from private citizens at the discretion of the Division Director or Section Supervisor or Bureau Chief.

Verification of Orally Ordered Tests

When additional tests are requested by telephone, the caller is asked to follow up with a written request on letterhead, or an additional laboratory request form for the test(s) requested. The written request should be sent to the attention of the Specimen Accessioning Section or to the Section Supervisor. The additional test(s) will not be performed until the written request is received. With time sensitive tests, the specimen may be tested immediately and the results held until the written request is received. In this case the caller may fax the request to the Laboratory. The caller should obtain the proper fax number at the time of their request. To process and test a specimen without a written request, the oral request is recorded in the telephone log of the area receiving the call: **Exception: No HIV tests will be performed without written request at the time of testing.** All specimens will be discarded if a written request is not received within seven working days

Requesting Repeat Testing On a Serology Specimen

To request a repeat serology test call Specimen Logistics, (803) 896-0898. Specimens are discarded after seven working days. A retest request must be made within that time period. Repeat testing on the same specimen may not always be feasible. The caller may be asked to briefly provide some patient clinical information and history to assist in determining the best approach. In some cases, a second (new) specimen for testing may be recommended. In other cases, the patient's clinical history may provide an explanation for the initial result, and retesting may not be necessary.

Specimens Referred for Testing To CDC

Laboratories wishing to send specimens directly to CDC should contact Diagnostic Microbiology Division, (803) 896-0965. The sender will be assigned a State Health Department number and will be asked to fax or mail to the Laboratory a copy of the information being sent. CDC forms are also available from the Laboratory.

Other Reference Laboratories

If a specimen is sent to a reference laboratory for initial, follow-up or verification testing by the Bureau of Laboratories, the sender will the notified that the specimen has been referred. The original result report from the reference laboratory is forwarded or faxed to the sender. A copy of the report is maintained by the laboratory.

STAT Testing

Requests received in the morning mail will be put in the day's run. The results will be telephoned to the

requestor, followed by a hard copy report. If the request is for a test that will not be performed immediately, the requestor will be informed by telephone when the test will be performed and the result available.

Confirmatory Testing

When confirmatory tests are necessary, patient results are not released until all testing is completed.

Laboratory Specimens Sent To the Bureau of Laboratories in Error

Specimens sent to the laboratory in error will be returned to the sender as soon as possible.

Correction of Patient Information

If a sender wishes to have an error corrected which was made on the original request form i.e. name not spelled correctly by sender, the sender must send a written statement on letterhead to the Specimen Accessioning Section indicating both the incorrect information and the correct information. The patient's record will be updated to reflect the change and a corrected report will be mailed to the sender.

A mislabeled specimen may not be known until the laboratory is notified that a report is in error because no specimen was collected from that patient. If the laboratory records are in order (the report, request and specimen are identified with the same name), the report will be re-mailed with a disclaimer. The submitting facility will be requested to submit a specimen on the correct patient if it is known which patient should have been tested.

Premarital Testing

There is no premarital testing requirement to obtain a marriage license in South Carolina.

The Bureau of Laboratories has the required premarital forms from all states with premarital testing requirements. A signed form for the state named will be returned to the requesting facility along with the result report. Call 803-896-0801 for additional information.

States Requiring Pre-Marital Testing

F=Female

INDIANARubella (F)MASSACHUSETTSSyphilisMISSISSIPPISyphilis

MONTANA Rubella (F), exemption granted by physician

OKLAHOMA Syphilis
DISTRICT OF COLUMBIA Syphilis
PUERTO RICO Syphilis

SPECIMEN REJECTION& DISCLAIMER CRITERIA

These are considered Universal rejections as they apply to all specimens submitted for testing. Specific Test related rejections are listed in the Alpha Test section and the collection procedures.

No Specimen Received

When a request form is received without a specimen, a computer inquiry is made to determine if the specimen has been received with another test request. If so, the specimen is obtained and aliquoted for all tests. If no specimen is found, the request form is numbered, processed, and reported "No specimen received."

No Request Form Received

If a specimen is received without a request form and the sender cannot be identified from the specimen label, the specimen will be held for seven days awaiting telephone inquiry or delayed receipt of form. After seven days the specimen is discarded.

No Name on Specimen

When a specimen is received without an identifying number or patient name, it WILL NOT be tested. An exception may be made for a specimen that cannot be recollected because of its unique anatomic source, collection method or time of collection. Examples include: CSF, peritoneal pleural and synovial fluids, autopsy, biopsy, or organ specimens, and specimens collected prior to the initiation of antimicrobial therapy.

No Name on Request Form

When a request form is received without a name, and there is no other identification on the form that matches the information on the specimen, the specimen will be reported as "No name on form."

No Test Requested

If the Test requested block is not marked on the request form and the sender is known, the specimen will be held and the sender notified by phone, fax or mail to send a corrected request form. When received, the specimen will be tested. If the test needed can be determined by the specimen container or test request form, i.e. OraSure, blood lead, or the test needed is written on the specimen label. The test will be added to the request form and the specimen processed as usual.

Other Missing Information

If other necessary information is missing, the specimen will be tested and the missing information will be requested by phone or by mail. The result will be held until the missing information is received.

Mismatched Information:

When the name on the request form and the specimen do not match, the specimen will not be tested .It will be reported as "Name on specimen differs from name on request form."

Partial Information Matches

When there is a partial name match and other data on the request form indicates it is most probably the same patient, (Patient ID or SS Number), the name on the tube is written on the request form, and the test is run and a disclaimer added to the report.

Specimen rejections, con't

Requesting Corrections

All requested changes to the request form by the sender must be documented on letterhead, dated and signed by the requestor. A returned copy of the original laboratory report requesting the missing information is acceptable to communicate changes needed as long as the sender states clearly what is needed, dates, and signs or photocopy the report.

Specimen Broken or Leaking in Transit

When a broken or leaking specimen is received, every attempt will be made to salvage it without compromising the integrity of the specimen. An exception is made for a Cytology slide that is broken (not crushed) and can be reconstructed, and for TB Culture of sterile body fluids.

Incorrect Specimen Received:

If the specimen received is incorrect for the test requested, a search is initiated to determine if the correct specimen was received with a request form for a different test. If the specimen is found, testing will be done. If the specimen is not found, the specimen is reported as "incorrect specimen received."

Unsatisfactory Specimens

The Bureau of Laboratories will not examine and will discard specimens which are received in unsatisfactory condition. The reasons for the rejection will be reported to the sender on the standard laboratory report form. Unsatisfactory conditions include but are not limited to:

Hemolyzed, chylous, or contaminated specimen,

Specimen received beyond the acceptable time for testing,

Specimen taken too soon or too late in the illness for the test requested,

Specimen was stored and shipped at improper temperature,

Specimen is nonviable, or decomposed

Specimen quantity insufficient

Specimens that have some degree of hemolysis, are icteric, or chylous, will be tested if the degree of hemolysis or lipemia does not interfere with the examination. The undesirable condition will be indicated on the report form.

RESULTS REPORTING POLICIES

All laboratory reports generated are considered confidential information. The reports will be released only to authorized persons. Electronic transfer of results is available to DHEC county health departments and some private sector clients. Contact the laboratory at 803-896-0810 for more information.

Reporting Schedule

Results are routinely processed for mailing or electronic reporting twice daily. On Fridays and on the last working day before a holiday any reports printed after courier pickup are mailed.

Telephone Results

Panic or Critical Values or Life-Threatening results and/or public health emergencies are telephoned to the appropriate person. A result will not be left on voice mail or an answering machine. A message to call the Bureau of Laboratories for a report will be left.

Copies of Reports:

- 1. Rabies testing: One copy is sent to the sender and one to the county health department.
- 2. Newborn Screening: One copy is sent to the hospital submitting specimen and one to the physician whose name has been entered on the request form. If no attending physician is listed, two copies are sent to the hospital.
- 3. All other tests: One copy is returned to the name entered in the sender section of the request form. We regret that we cannot honor requests for multiple copies. If multiple copies of other test reports are needed, we suggest you photocopy the original report issued.

Remailing of Results Reports

If a physician or clinic to which the patient has been referred requests a copy of a test result, the report will be reprinted with the original sender number and mailed as requested. If, for some reason, you do not receive a report, you may obtain a copy by calling 803-896-0898.

Correcting Reporting Errors

If an error or the possibility of an error is discovered by the laboratory after results have been mailed, the sender will be notified immediately by telephone. The error will be explained and the correct result given. A corrected hard-copy report will be issued with the comment "Corrected Report" at the next printing.

If an error in reporting is discovered by the sender, the laboratory should be notified immediately. The error will be corrected and a corrected report will be mailed. The corrected report will be printed with the comment "Corrected Report".

DISEASE REPORTING

The Code of Laws of South Carolina (1976) Section 44-29-10: Regulation 61-20 mandates that the Commissioner of DHEC is to publish annually a list of diseases to be reported by physicians and laboratories. This list can be found on the internet at scdhec.net/hs/diseasecont/disease.htm.

All communicable disease outbreaks and unusual disease occurrences should be reported so that appropriate control measures can be implemented.

SECTION II

ALPHA LISTING OF TEST INFORMATION

ABO GROUPING

Available only to DHEC clinics

Synonyms: Blood grouping

Test Section: Clinical Labs Section, Hematology/ Immunohematology unit, 803-896-0954

Days Test Performed: Monday-Friday **Request Form:** DHEC 1332, Test # 701

Special Instructions: See Venipuncture procedure Section III, if needed

Specimen & Volume: 5-7ml. EDTA anticoagulant whole blood & 5-7 ml whole clotted blood

Container: One Lavender Top (EDTA) and 1 Red Top Vacuum Tube **Storage/Shipping Temperature:** Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I

Methodology: Hem agglutination

Add. Information: Identifies blood as Group A, Group B, Group O, Group AB

CPT Code: 86900

ACANTHAMOEBA CULTURE - See "Amoeba Culture"

ACID FAST BACILLI CULTURE (AFB) - See "Mycobacterial Culture"

ADENOVIRUS CULTURE

Synonyms: Respiratory Virus culture **Test Section:** Virology, 803-896-0820/0819 **Days Test Performed:** Monday-Friday **Request Form:** DHEC 1335, Test #270

Special Instructions: Collect specimen while patient is acutely ill and febrile

See viral culture collection procedure, section III

Specimen & Volume: Throat swab, N-P swab, Eye swab, Rectal swab, walnut sized portion of feces, 5-10 ml Urine, 1 ml, CSF, small piece fresh, unfixed Tissue, or 10 ml, EDTA anti-coagulated whole blood

Container: Screw capped tube of viral transport media for swabs, (provided on request), clean plastic container for feces or urine, Lavender Top (EDTA) vacuum tubes for blood, and Screw cap collection tube for CSF

Storage/Shipping Temperature: Store in refrigerator Ship cold with cold packs. If held longer than 48 hours, freeze at -70 °C and ship on dry ice except for blood. **Blood should not be frozen**

Shipping Description: Diagnostic Specimen See packing and shipping instructions, section IV **Rejection Criteria, specific**: Calcium alginate swab used, specimen not cold on arrival. For

universal rejections, see Section I

Methodology: Cell culture; ID by FA

Add. Information: NA

CPT Code: Culture 87252; Identification 87253

AEROBE REFERRED FOR IDENTIFICATION (Bacterial)

Synonyms: Aerobic Culture; Salmonella, Shigella, Campylobacter, Pseudomonas, Streptococcus,

etc.; culture for identification

Test Section: Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #511

Special Instructions: NA

Specimen & Volume: Pure bacterial isolate

Container: Screw-capped tube containing agar slant that will support growth of isolate

Storage/Shipping Temperature: Store & ship at Room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Culture nonviable; culture mixed. For universal rejections, see

Section I

Methodology: Conventional bio-chemicals

Add. Information: NA

CPT Code: 87077

AIDS TESTING - See "HIV"

ALCOHOL SCREEN - See "Drugs of Abuse Screen, Urine"

AMOEBAE CULTURE

Synonyms: Acanthamoeba culture, Naegleria culture **Test Section:** Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #41100

Special Instructions: Notify Parasitology lab prior to submission. Protect specimen from cold

Specimen & Volume: 1 ml CSF or small piece of tissue (brain, lung, corneal scrapings) **Container:** Sterile, screw-capped tube containing small amount of Page's amoeba saline

Storage/Shipping Temperature: Store and ship at Room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Specimen refrigerated or frozen. For universal rejections, see

Section I

Methodology: Culture and microscopic examination

Add. Information: Culture for the presence of Acanthamoeba or Naegleria

CPT Code: 87181

AMPHETAMINES SCREEN - See "Drugs of Abuse Screen, Urine"

ANTIBODY SCREEN

This test is only performed as part of the prenatal screen for DHEC clinics

Synonyms: Indirect coombs

Test Section: Clinical laboratories section, immunohematology unit 803-896-0954

Days Test Performed: Monday-Friday **Request Form:** DHEC 1332, Test # 702

Special Instructions: Do NOT use serum separator tube; Separate serum from clot. Specimen

must be less than 48 hours old when tested See Venipuncture procedure, Section III, if needed

Specimen & Volume: 5-7 ml blood or 2 ml serum

Container: Sterile RED TOP vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, **Specific:** Serum separator tube used; specimen too old.

For universal rejections, see Section I **Methodology:** Antiglobulin test

Add. Information: Interpretation: Negative- antibody not detected:

Equivocal or positive-Sent to reference lab for confirmation, ID and titer if necessary

CPT Code: 86885

ANTICONVULSANT DRUG MONITORING

This test is only performed for DHEC clinics

Synonyms: Therapeutic drug Monitoring, Antiepileptic drugs

Test Section: Clinical laboratories section, Toxicology unit 803-896-0890

Days Test Performed: Monday-Friday **Request Form:** DHEC 1332, Test #810

Special Instructions: Testing available for 4 drugs: Phenytoin, phenobarbital, Carbamazepine, and

Valproic acid. Order test individually

Specimen & Volume: 3 ml serum. See Venipuncture procedure, Section III

Container: Sterile RED TOP vacuum tube; do not send SST tubes for Phenytoin(Dilantin)

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen. See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I

Methodology: Enzyme Immunoassay (EIA)

Add. Information: NA

CPT Code: 80185 Phenytoin; 80184 Phenobarb; 80156 Carbamazepine; 80164 Valproic acid

ARBOVIRUS SEROLOGY

Synonyms: Test includes EEE, WEE, SLE, CAL and WNV (West Nile virus)

Test Section: Virology, 803-896-0819 **Days Test Performed:** Weekly

Request Form: DHEC 1332, Test # 117

Special Instructions: Paired specimens NOT required See Venipuncture procedure, Section III

Specimen & Volume: 5 ml blood or 2 ml serum

Container: Red top vacuum tube

Arbovirus Serology cont.

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I

Methodology: IFA for Arboviruses, EIA for West Nile virus

Add. Information: Titer of < 1:16 is considered negative for arboviruses, <1:400 considered

negative for WNV

CPT Codes: EEE 86652, WEE 86654, SLE 86653, CEE 86651, WNV 86790

ARBOVIRUS DETECTION BY PCR

Synonyms: Arbovirus PCR. Test includes EEE, WEE, SLE, CAL, LAC, and WNV

Test Section: Molecular Epidemiology 803-896-0825

Days Test Performed: Weekly

Request Form: DHEC 1335, Test #113

Special Instructions: For testing to be initiated the following information MUST be provided: Date of onset, date specimen collected, and any pertinent travel history or exposure. Specimen must be collected within 10 days following onset of symptoms

Specimen & Volume: 1 ml CSF minimum **Container**: Screw capped CSF collection tube

Storage/Shipping Temperature: Store in refrigerator. Ship on wet ice or with cold packs. If shipping, is delayed > 48 hours, freeze at $-20^{\circ C}$ and ship on dry ice.

Shipping Description: Infectious substance See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I

Methodology: Real time reverse transcriptase polymerase chain reaction (RT-PCR) is used to detect West Nile virus (WNV), Eastern Equine encephalitis (EEE), St. Louis

encephalitis (SLE), and La Crosse. California serogroup is tested using standard RT-PCR.

Add. Information: This test is used to detect the presence of Arboviral RNA in clinical CSF specimens. RT-PCR results are positive or negative for the presence of the Arbovirus

CPTCode: 83890 extraction; 83894 gel electrophoresis; 83898 amplification; 83902 reverse transcriptase

BACTERIAL ISOLATE, REFERRED FOR ID - See Aerobe referred.

BARBITURATE SCREEN, URINE - See "Drugs of Abuse Screen"

BENZOYLECGONINE - See "Cocaine Screen"

BETA-HEMOLYTIC STREPTOCOCCUS, GROUP A CULTURE

Synonyms: Beta Strep culture; Throat culture; group A strep or *Streptococcus pyogenes* culture

Test Section: Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #509

Special Instructions: See culture collection procedure, Section III

Specimen & Volume: One (1) Throat swab. **Container:** Culturette tube with transport medium

Storage/Shipping Temperature: Store and ship at room temp; ship as quickly as possible Shipping Description: Diagnostic specimen. See packing & shipping instruction, Section IV Rejection Criteria, specific: Ampoule in transport tube not crushed; specimen in transit

more than 2 days. For universal rejections, see Section I **Methodology:** Conventional culture methods

Add. Information: NA

CPT Code: 87070

BETA-HEMOLYTIC STREPTOCOCCUS, GROUP B CULTURE

Synonyms: Group B Strep culture, strep vaginal culture, *Streptocuccus agalactiae* culture

Test Section: Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #510

Special Instructions: See culture collection procedure, Section III

Specimen & Volume: One (1) Swab

Container: Culturette

Storage/Shipping Temperature: Store and ship at room temp; ship as quickly as possible Shipping Description: Diagnostic specimen. See packing & shipping instruction, Section IV Rejection Criteria, specific: Ampoule in culturette not broken, swab contaminated with feces,

specimen in transit more than 2 days. For universal rejections, see Section I

Methodology: Conventional culture methods

Add. Information: NA

CPT Code: 87070

BLOOD LEAD -See Lead, Blood

BLOOD PARASITE EXAMINATION - See "Malaria Smear"

BORDETELLA PERTUSSIS CULTURE

Synonyms: Pertussis, whooping cough; B. pertussis culture; **Test Section:** Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #510

Special Instructions: See collection procedure for PCR and culture, Section III Regan-Lowe medium must be warned to room temperature prior to inoculation.

Immerse swab into medium <u>immediately</u> after collection. Use swab with Dacron or Rayon tip. DO NOT

USE cotton or calcium alginate swab.

Specimen & Volume: Nasopharyngeal swab preferred; Throat swab acceptable.

Container: Regan-Lowe transport tube (Available upon request from BOL Media Section) **Storage/Shipping Temperature:** Store and ship at room temperature; If shipping is delayed, specimen may be incubated aerobically at 35°C for up to 48 hours prior to shipping

Shipping Description: Diagnostic specimen. See packing & shipping instruction, Section IV

Rejection Criteria, specific: Regan-Lowe media not used or media expired; Cotton swab used.

For universal rejections, see Section I

Methodology: Conventional culture methods

Add. Information: NA

CPT Code: 87070; culture; 87077 ID

BORDETELLA PERTUSSIS DNA BY PCR

Synonyms: Pertussis, Whopping cough

Test Section: Molecular Epidemiology, 803-896-0825

Days Test Performed: Monday-Friday **Request Form:** DHEC 1335, Test #115

Special Instructions: Use swab with <u>Dacron or Rayon</u> tip. DO NOT USE cotton or calcium

alginate swab.

Specimen & Volume: Two (2) nasopharyngeal swabs (one swab for the right nare and one swab

for the left nare. See collection procedure for PCR and culture, section III.

Container: Sterile 50 ml. polypropylene conical tube or tube provided in collection kit

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs.

Specimen must be shipped within 48 hours.

Shipping Description: Diagnostic Specimen. See packing & shipping instructions, Section IV Rejection Criteria, specific: Cotton or calcium alginate swab used; Specimen not cold on

arrival; specimen too old. For universal rejections, see Section I.

Methodology: Real-time PCR

Add. Information: This test is used to detect the presence of *B. pertussis* nucleic acid (DNA)

CPT Code: 83890 extraction; 83898 amplification

BOTULISM

Prompt diagnosis and early treatment of botulism are essential to minimize the otherwise great risk of death. State Health Departments and the Center for Disease Control & Prevention (CDC) offer 24-hour diagnostic consultation, epidemic investigation assistance, and laboratory services. Trivalent (ABE) Botulinal Antitoxin is available from the CDC. In order to receive these services, it is necessary to do the following:

- 1. Contact the DHEC/Bureau of Epidemiology, Disease Control & Surveillance consultant at (803) 898-0861 (M-F during business hours) or digital pager (803) 690-3756 (after hours).
- 2. If appropriate, call the CDC Emergency 24 hour number (770-488-7100) to make arrangements for immediate shipment of the antitoxin, when indicated, and for proper shipment of selected clinical specimens and/or food samples for testing.
- 3. Contact the DHEC Division of Diagnostic Microbiology (**803-896-0870 or 0966**) to obtain faxed copy of CDC request form and State Laboratory number.

BREAST SMEAR CYTOLOGY -See PAP smear/ Breast smear Cytology

CAMPYLOBACTER - See "Stool Culture for Enteric Pathogens"

CBC

Synonyms: Complete Blood Count with Differential

Test Section: Clinical Laboratories Section, Hematology Unit – 803-896-0954

Days Test Performed: Monday – Friday **Request Form:** DHEC 1332, Test# 760

Special Instructions: Specimen must be less than 24 hours old when tested by laboratory. **Specimen Volume:** 3 ml EDTA anticoagulated whole blood (dependent upon whether cells are

badly distorted by excess anticoagulant) Mix well by gentle inversion.

Container: Lavender top(EDTA)vacuum tube. See Venipuncture procedure, Section III, if needed. Storage/Shipping Temperature: Store and ship at room temperature. Do not refrigerate. Shipping Description: Diagnostic Specimen. See packing and shipping instructions Section IV. Rejection Criteria, specific: Specimens more than 24 hours old upon arrival, specimen platted, and specimen received cold or frozen. For universal rejections, see Section IV.

clotted, and specimen received cold or frozen. For universal rejections, see Section I.

Methodology: Automated Cell Counter

Add. Information: None

CPT Code: 85025

CD4 - See "Lymphocyte Subset"

CELLOPHANE TAPE PREP - See "Pinworm Exam"

CHAGAS DISEASE - See "Parasite Serology"

CHLAMYDIA (CT) DETECTION BY NUCLEIC ACID AMPLIFICATION

Synonyms: Gen-Probe, C. trachomatis Amplified Nucleic Acid Probe, Chlamydia rRNA,CT Aptima

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test #506 - Chlamydia; Test #507 - Chlamydia and GC.

Special Instructions: Only use Gen-Probe Aptima Combo 2 specimen collection kit(swab or urine). Patients under the age of twelve should be tested by culture. **Same specimen can be used for both CT and GC See collection procedure, Section III**

Specimen & Volume: Swab specimen: Endocervical and/or male urethral Gen-Probe blue-shafted swab in Gen-Probe Aptima Combo 2 transport media. Vaginal specimens will be tested, but reported with a disclaimer. An alternate specimen for the vaginal specimen would be a urine specimen. <u>Urine specimen</u>: Patient should not have voided within one hour of collection. Collect 20-30 ml of the first-catch urine stream. Transfer 2 ml. of urine into urine transport tube so that the urine level falls within the two lines on the transport tube labeled: "fill area".

Container: Gen-Probe Aptima Combo 2 Unisex transport kit for swabs.

Gen-Probe Aptima Combo 2 Urine specimen transport tube for urines.

Storage/Shipping Temperature: Store and ship at Room temperature; Swab specimens must be tested within 60 days of collection, and Urine specimens within 30 days of collection.

Shipping Description: Diagnostic specimen. See packing & shipping instructions, Section IV

CHLAMYDIA DETECTION, cont.

Rejection Criteria, specific: Specimen from non-genital site(other than urine); No swab or white swab in transport media; 2 swabs in transport media; Urine above or below designated black lines on transport tube labeled fill area; Swab specimen more than 60 days old, or urine specimen more than 30 days old when received. For universal rejections, see Section I.

Methodology: Target amplification Nucleic acid Probe

Add. Information: This test is not appropriate in cases of sexual assault or abuse;

Patients under the age of twelve should be tested by culture

CPT Code: 87491 for CT only; use 87491 and 87591 (GC) for combination test

CLINICAL CHEMISTRY

Panels available to DHEC clinics only

CHEMISTRY	CHEMISTRY	CHEMISTRY	CPT
GENERAL PANEL I	GENERAL PANEL II	GENERAL PANEL III	CODE
	DE: Use individual analyte code		
Glucose	Glucose	Glucose	82947
Uric Acid	Uric Acid	Uric Acid	84550
Cholesterol, total	Cholesterol, total	Cholesterol, total	82465
AST (SGOT)	AST (SGOT)	AST (SGOT)	84450
Total Protein	Total Protein	Total Protein	84155
Albumin	Albumin	Albumin	82040
Globulin*	Globulin*	Globulin*	NA
Total Bilirubin	Total Bilirubin	Total Bilirubin	82247
Calcium	Calcium	Calcium	82310
BUN	BUN	BUN	84520
Creatinine	Creatinine	Creatinine	82565
	BUN/Creatinine Ratio*	BUN/Creatinine Ratio*	NA
	Alkaline Phosphatase	Alkaline Phosphatase	84075
	Phosphorus	Phosphorus	84100
	LDH	LDH	83615
	ALT (SGPT)	ALT (SGPT)	84460
		Sodium	84295
		Potassium	84132
		Chloride	82435
		Triglycerides	84478
		CK	82550
		GGT	82977

LIPID PANEL with GLUCOSE CPT CODE: 80061, 82947	LIVER PANEL CPT CODE: 80076 + 82465 (cholesterol)	TB PANEL	CPT CODE:
Cholesterol, Total	AST (SGOT)	AST (SGOT)	84450
Triglycerides	ALT (SGPT)	ALT (SGPT)	84460
HDL	Alkaline Phosphatase	Total Bilrubin	82247
LDL*	Total Bilirubin	Alkaline Phosphatase	84075
Glucose	Cholesterol	Uric Acid	84550
	Total Protein	BUN	84520
	Albumin	Creatinine	82565
	Globulin*	Glucose	82947
	LDH		

^{*}Calculated Values have no CPT codes and cannot be billed

CLINICAL CHEMISTRY, CONT

Synonyms: Serum Chemistries,

Test Section: Clinical Laboratories, Clinical Chemistry Unit, 803-896-0891

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test # 710- 719 (varies with panel) **Special Instructions**: Lipid panel requires fasting specimen

Specimen & Volume: 2-5 ml serum **See Venipuncture procedure, Section III, if needed**.

Container: Vacutainer tube or SST

Storage/Shipping Temperature: Store and ship at room temperature except during hot

weather ship under refrigeration

Shipping Description: Diagnostic specimen. See packing & shipping instructions, Section IV

Rejection Criteria, specific: none. For universal rejections, see Section I.

Methodology: Automated Chemistry analyzer

Add. Information: None

CPT Code: Must use individual analyte codes. See previous page

CMV - See "Cytomegalovirus Culture"

COCAINE & MARIJUANA SCREEN, URINE

Synonyms: Benzoylecgonine & Cannabinoids, Drugs of Abuse Screen **Test Section:** Clinical Laboratories section, toxicology unit, 803-896-0891

Days Test Performed: Monday - Friday **Request Form:** DHEC 1332, Test #813

Special Instructions: See urine drug screen Chain-of-Custody protocol, Section III, if needed

Specimen & Volume: 25 ml Random urine

Container: Plastic urine container

Storage/Shipping Temperature: Store and ship at room temperature; Refrigerate if longer

than 24 hours before shipping.

Shipping Description: Considered non-infectious. **DO NOT** put biohazard label on outside of shipping container. **See packaging and shipping instruction under COC collection protocol, section III.**

Rejection Criteria, specific: None. For universal rejections, see Section I.

Methodology: Enzyme Immunoassay (EIA)

Add. Information: None **CPT Code:** 80101 each drug

COMPLETE BLOOD COUNT- See CBC

CONGENITAL ADRENAL HYPERPLASIA - See "Newborn Screening"

CORYNEBACTERIUM DIPHTHERIAE, CULTURE & ID

Synonyms: C. diphtheriae

Test Section: Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday-Friday

Request Form: DHEC 1335, Test #510 (clinical material or swab) or Test #511 (referred isolate)

Special Instructions: NA

Specimen & Volume: Throat swab; referred isolate

Container: Submit swab in transport tube (culturette), submit referred isolate on agar slant in screw

capped tube See bacterial culture collection, Section III

Storage/Shipping Temperature: Store & ship at room temperature

Shipping Description: Diagnostic specimen: See packing & shipping instructions, Section IV

Rejection Criteria, specific: Culturette not used or Ampoule in culturette not crushed (throat

swab). For universal rejections, see Section I.

Methodology: Conventional culture methods

Add. Information: Detection of *Corynebacterium diphtheriae*

CPT Code: 87070, culture; 87077 ID

COXSACKIE VIRUS A & B CULTURE - See "Enterovirus Culture"

CRYPTOSPORIDIUM STAIN

Synonyms: NA

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #406

Special Instructions: None

Specimen & Volume: Walnut-sized portion Fresh stool or 3 ml of liquid stool, formalin preserved

stool, duodenal fluid, or bile

Container: Transport tube in kit

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Specimen preserved in PVA; improper labeling. For universal

rejections, see Section I.

Methodology: Microscopic exam of acid fast stained smear; FA stain **Add. Information:** To detect the presence of Cryptosporidium oocysts

CPT Code: 87015, 87272

CYCLOSPORA

Synonyms: C. cayetanensis

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #410

Special Instructions: None

Specimen & Volume: Walnut-sized portion of fresh stool; or walnut-sized portion of feces in 15

ml of 10 % formalin

Container: Screw-capped tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen preserved in PVA **Methodology:** Microscopic exam of acid-fast stained smears **Add. Information:** To detect the presence of cyclospora

CPT Code: Concentration 87015, stain 87206

CYSTICERCOSIS - See "Parasite Serology"

CYTOLOGY, BREAST SMEAR.-see PAP smear/Breast smear Cytology

CYTOLOGY, PAPS SMEAR.-see PAP smear/Breast smear Cytology

CYTOMEGALOVIRUS CULTURE

Synonyms: CMV

Test Section: Virology, 803-896-0819 **Days Test Performed:** Monday-Friday **Request Form:** DHEC 1335, Test #273

Special Instructions: Refrigerate immediately upon collection.

Specimen & Volume: Urine (preferred specimen); tissue; Buffy coat (submit 2 EDTA tubes),

bronchial washing, CSF

Container: Plastic urine container

Storage/Shipping Temperature: Ship COLD within 24 - 48 hours. DO NOT FREEZE Shipping Description: Diagnostic specimen. See packing and shipping instructions, section IV. Rejection Criteria, specific: Specimen not cold on arrival; specimen frozen; specimen too old.

For universal rejections, see Section I.

Methodology: Cell culture

Add. Information: Preliminary report on urine (shell vial culture) reported within 48 hours. No

preliminary report on tissue, sputum, feces or CSF **CPT Code:** Culture 87252; Identification 87253

DAIRY PRODUCTS EXAMINATIONS

The Dairy Products Section performs test on dairy products to assure the public that the standards for bacterial limits and butterfat levels as defined by the S.C. Milk Standards and Regulations are maintained and that milk is free of antibiotics or added water. Products from each dairy in S.C. are examined at least eight times a year. Tests are performed on pasteurized milk and other dairy products including creams, ice creams and other frozen desserts. Raw milk from dairy farms is tested with the same frequency.

Samples are collected by environmentalists from the DHEC Dairy Division.

If milk or other dairy products are believed to be the cause of a food borne illness, the sample is handled through the county health department, and is tested in the Food Laboratory of the Bureau of Laboratories.

Please call the Environmental Health Section of your local County Health Department for help.

DIPHTHERIA - See Corynebacterium diphtheriae

DRUGS OF ABUSE SCREEN, URINE

Synonyms: <u>Panel Includes</u>: Amphetamine, Barbiturate, Cannabinoid, Opiate, Cocaine, Benzodiazepine, Propoxyphene, Methadone, Methaqualone, Phencyclidine and Alcohol

Test Section: Toxicology/Clinical Chemistry, 803-896-0891

Days Test Performed: Monday – Friday **Request Form:** DHEC 1332, Test #811

Special Instructions: See chain-of-custody protocol, Section III, if desired

Specimen & Volume: 30 ml. random urine

Container: Plastic urine container

Storage/Shipping Temperature: Store and ship at room temperature; Refrigerate if longer

than 24 hours before shipping

Shipping Description: Does not require hazard marking. DO NOT use Biohazard sticker on

outside of shipping container. See packing and shipping instructions, Section IV

Rejection Criteria, specific: Break in Chain -of -custody if COC specimen. For universal

rejections, see Section I.

Methodology: Enzyme Immunoassay

Add. Information: NA

CPT Code: 80101(X 12 classes). For confirmation of positives, add 80102.

EASTERN EQUINE ENCEPHALITIS - See "Arbovirus Serology"

ECHO - See "Enterovirus Culture"

E. COLI O157 - See "Enteric Pathogens Culture"

ENCHINOCOCCOSIS - See "Parasite Serology"

ENTERIC PATHOGENS CULTURE

Synonyms: Fecal Culture, Enteric Culture, Salmonella Culture, Shigella Culture

Test Section: Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #508

Special Instructions: See Enteric collection procedure, Section III.

Specimen & Volume: Walnut sized portion of Feces or 5-10 ml of liquid stool. Infant specimens may be collected in a disposable diaper with plastic side facing inside.

Container: Transport tube in Enteric Kit with Cary-Blair medium

Storage/Shipping Temperature: Stools not in medium must be shipped with cold packs to arrive in the laboratory and be inoculated within 24 hours of collection. If specimen is in transport medium, store and ship under refrigeration to be received at the lab within 48 hours of collection.

Shipping Description: Diagnostic Specimen. See packing & shipping instructions, Section IV

Rejection Criteria, specific: Quantity insufficient; specimen too old; improper transport media or conditions. For universal rejections, see Section I.

Methodology: Conventional culture methods and biochemicals; Serological tests for *Shigella*, *E. coli* 0157:H7, *V.cholera* and *Salmonella* including Salmonella serotyping

Add. Information: NA

CPT Code: 87045 Salmonella and Shigella Culture; 87046 all others; Use 87077 for ID.

ENTEROBIUS VERMICULARIS - See "Pinworm Exam"

ENTEROVIRUS CULTURE

Synonyms: Includes - ECHO, Coxsackie, Polio

Test Section: Virology, 803-896-0819 **Days Test Performed:** Monday - Friday **Request Form:** DHEC 1335, Test #270

Special Instructions: See Virus culture collection procedures, Section III Specimen & Volume: Throat swab, rectal swab, N-P swab, feces, CSF

Container: Dry tube for feces, CSF collection tube, or tube of Viral transport media for swab.

Storage/Shipping Temperature: Store in refrigerator and ship cold with cold packs within 24-48 hours. If shipping is delayed, freeze specimen and ship on dry ice.

Shipping Description: Diagnostic Specimen. See packing & shipping instructions, Section IV

Rejection Criteria, specific: Specimen not cold on arrival; specimen too old. For Universal

rejections, see Section I.

Methodology: Cell culture Add. Information: NA

CPT Code: Culture 87252; ID 87253

ENVIRONMENTAL LEAD- See Lead. Environmental

FILARIASIS - See "Parasite Serology"

FOOD-BORNE ILLNESSES (FOOD POISONING)

The Food Laboratory assists in the epidemiological investigation of suspected foodborne illness. A physician with a patient suspected of having a food borne illness should contact Food Protection in the county health department. The laboratory does not accept samples from individuals.

GALACTOSEMIA - See "Newborn Screening"

GC CULTURE - See "Gonococcal Culture"

GEN-PROBE ANTIGEN DETECTION - See GC and Chlamydia antigen detection

GERMAN MEASLES - See "Rubella"

GIARDIA - See "Trichrome Stain" or "Parasite Examination"; General (O and P)

GIEMSA STAIN - See "Malaria Smear"

GONOCOCCAL (GC) DETECTION NUCLEIC ACID AMPLIFICATION

Synonyms: Gen-Probe *N. gonorrhoeae* Amplified Nucleic Acid Probe, Gonorrhea rRNA,

GC Aptima

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday

Request Form: DHEC 1332, Test #505-GC only; Test #507 - GC and Chlamydia

Special Instructions: Only use Gen-Probe Aptima Combo 2 specimen collection kit

Materials (swab or urine). Patients under the age of twelve should be tested by culture.

Specimen & Volume: <u>Swab specimen:</u> Endocervical or male urethral Gen-Probe blue-shafted swab in Gen-Probe Aptima Combo 2 Transport media. Vaginal samples will be tested but reported with a disclaimer. An alternate specimen for the vaginal specimen would be a urine specimen. **See GC/Chlamydia Gen-probe collection procedure, Section III**

Container: Gen-Probe Aptima Combo 2 Unisex transport kit for swabs.

Gen-Probe Aptima Combo 2 Urine specimen transport tubes for urines.

Storage/Shipping Temperature: Store and ship at room temperature; Swab specimens must be tested within 60 days of collection; Urine specimens within 30 days of collection. **Shipping**

Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen from non-genital site(other than urine); No swab or white swab in tube; 2 swabs in one tube; Urine above or below designated black lines on transport tube labeled fill area; swab specimen more than 60 days old; Urine specimen more than 30 days old.. For universal rejections, see Section I.

Methodology: Target Amplification Nucleic acid Probe

Add. Information: This test is not appropriate in cases of sexual assault or abuse.

Patients under the age of 12 should be tested by culture.

CPT Code: 87591 GC only. Use 87491 and 87591 for combination test

GONOCOCCAL (GONORRHEA) CULTURE

Restricted to County Health Departments only

Synonyms: GC culture, *Neisseria gonorrhoeae* culture **Test Section:** Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #501

GONOCOCCAL (GONORRHEA) CULTURE, CONT

Special Instructions: Bring transgrow bottle to room temperature before inoculating: <u>hold bottle</u> upright and roll swab over entire surface of medium; discard swab.

Specimen & Volume: See N. gonorrhoeae collection procedure, Section III

Container: Transgrow bottles. DO NOT PLACE LABEL ON CLEAR SIDE OF BOTTLE

Storage/Shipping Temperature: If an incubator is available, incubate inoculated transgrow bottle upright at 35° C. until shipped, and indicate incubation time on Request Form. Specimens collected on Friday can be incubated until Monday, but remove first thing Monday morning to prevent overgrowth of contaminants. If an incubator is not available, make sure culture is shipped on the same day as collected. Health departments using the state courier may ship cultures on Friday and mark as not incubated. DO NOT REFRIGERATE AFTER INOCULATION. Do not use expired media

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV **Rejection Criteria**, specific: Transgrow media not used or media expired; specimen in transit more than 5 days. For universal rejections, see Section I.

Methodology: Carbohydrate fermentation or enzyme detection

Add. Information: NA

CPT Code: 87070 culture; and 87077 (ID)

GROUP A STREPTOCOCCUS - See Beta-Strep culture, group A

GROUP B STREPTOCOCCUS -See Beta-Strep culture, group B

HANTAVIRUS SEROLOGY- IgG/IgM

Synonyms: None

Test Section: Virology, 803-896-0819 **Days Test Performed:** As needed **Request Form:** DHEC 1332, Test #107

Special Instructions: Call prior to sending specimen; DO NOT remove serum from clot **Specimen & Volume:** 5 ml whole blood **See Venipuncture procedure, Section III, if needed**

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I.

Methodology: EIA

Add. Information: None

CPT Code: 86790

HEAVY METAL ANALYSIS - See Lead analysis...for others, call laboratory

HEMOGLOBIN (Hb) ELECTROPHORESIS

Synonyms: Sickle Cell screen Also part of newborn screening panel

Test Section: Newborn Screening, 803-896-0874

Days Test Performed: Monday - Friday **Request Form:** DHEC 1327, Test #90005

Special Instructions: See heel-stick specimen collection procedure, Section III

Specimen & Volume: Blood spots on filter paper or EDTA anticoagulated whole blood, 2 ml

Container: Filter paper or lavender top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing & shipping instructions, Section IV Rejection Criteria, specific: More than one month old; transfused; blood spots not properly collected. For universal minetions, see Section I.

collected. For universal rejections, see Section I.

Methodology: Iso Electric Focusing (IEF); High Performance Liquid Chromatography (HPLC)

Additional Information: NA

CPT Code: 83020

HEMATOLOGY- See CBC

HEMOLYTIC ANEMIA - See "Hemoglobin Electrophoresis"

HEPATITIS A SEROLOGY

Synonyms: HAV IgG and HAV IgM

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Upon request; See Special Instructions below.

Request Form: DHEC 1332, Test # 019- IgG Hepatitis A, Total; Test # 020- IgM Hepatitis A,

IgM

Special Instructions: HAV total antibody testing will be performed on all patients received for screening, with follow-up on all positive patients with Hepatitis A IgM. If patients suspected of having Hepatitis A and is not involved in an outbreak, request Hepatitis A IgM and total antibody. All Hepatitis A outbreak investigations should be reported to the laboratory supervisor (803-896-0811) or Division Director (803-896-0870) prior to shipment of specimens

Specimen & Volume: 0.5 ml whole blood or 0.25 ml serum or plasma **See Venipuncture collection procedure, Section III, if needed**.

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature Specimen must arrive at lab within 5 days of collection; If shipping is delayed more than 5 days after collection, freeze serum at – 20° C and ship on dry ice

Shipping Description: Diagnostic specimen See packing & shipping instructions, Section IV.

Rejection Criteria, specific: Improperly stored/shipped or contaminated specimens

For universal rejections, see Section I.

Methodology: EIA

Add. Information: A positive HAV IgG antibody result indicates a past or current HAV infection; A positive HAV IgM antibody indicates an acute HAV infection, one that is usually accompanied by clinical symptoms of acute hepatitis; The clinical symptoms of HAV may precede the laboratory detection of HAV IgM by a few days

CPT Code: 86708-IgG; 86709-IgM

HEPATITIS B CORE TOTAL ANTIBODY SCREEN

Synonyms: Anti-HBc

Test Section: Diagnostic Serology, 803-896-0811 Days Test Performed: Monday - Thursday Request Form: DHEC 1332, Test #226

Special Instructions: See Venipuncture procedure, Section III, if needed

Specimen & Volume: One (1) ml whole clotted blood, or 0.5 ml serum or plasma; Specimen must arrive at lab within 5 days of collection; If shipping is delayed more than 5 days after collection,

freeze serum at -20° C and ship on dry ice

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV **Rejection Criteria, specific:** Improperly stored/shipped specimens, grossly hemolyzed

and contaminated specimens

Methodology: EIA **Add. Information: NA**

CPT Code: 86704

HEPATITIS B DIAGNOSTIC PROFILE

Synonyms: NA

Test Section: Diagnostic Serology, 803-896-0811 **Days Test Performed:** Monday - Thursday Request Form: DHEC 1332, Test #223

Special Instructions: See Venipuncture procedure, Section III, if needed **Specimen & Volume:** 2-5 ml whole clotted blood, or 2 ml serum or plasma.

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature; Specimen must arrive at lab within 5 days of collection; If shipping is delayed more than 5 days after collection,

freeze serum at -20° C and ship on dry ice

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Improperly stored/shipped or contaminated specimens

For universal rejections, see Section I.

Methodology: EIA

Add. Information: Includes tests for HBsAg, anti-HBs, and anti-HBc. HBeAg, anti-HBe and anti-core IgM are performed if indicated.

Interpretations:

HbsAg	anti- HBs	Anti-HBc total antibody	Interpretation
1	-	-	No laboratory evidence of HBV infection. Does not rule-out "low level" HBV carrier state, or the" window" between the disappearance of HBsAg and the appearance of anti-HBs and anti-HBc IgG.
+	-	-	Early acute HBV infection.
+	±	+	HBV infection, either acute or chronic. Differentiate with anti-HBc IgM.
-	+	+	Previous HBV infection and immunity to HBV.
	+	-	Vaccine-type response indicating immunity to HBV.

CPT Code: 87340 surface antigen; 86706 surface antibody; 86704 core antibody; 87350 E antigen; 86707 E antibody

HEPATITIS B CORE IgM ANTIBODY

Test automatically performed on patients with reactive anti-HBcore total antibody in absence of reactive HBsAg or anti-HBs on Diagnostic Profile (test #223)

Synonyms: Anti-HBc IgM

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Available upon request. See special instructions below.

Request Form: DHEC 1332, Test #220

Special Instructions: Consultation between the requesting physician or district Medical Director

and the laboratory supervisor or Division Director is required prior to specimen testing

HEPATITIS B CORE IgM ANTIBODY, Cont.

Specimen & Volume: 0.5 ml whole clotted blood or 0.25 ml serum or plasma

Container: Red top vacuum tube preferred **See venipuncture procedure**, **section III**, **if needed**.

Storage/Shipping Temperature: Store and ship at room temperature.

Specimen must arrive at lab within 5 days of collection. If shipping is delayed more than 5 days after collection, freeze serum at -20° C and ship on dry ice.

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen will not be tested without prior consultation (See Special Instructions above); Improperly stored/shipped or contaminated specimens. For universal rejections, see Section I.

Methodology: EIA

Add. Information: A positive Anti-HBc IgM result in conjunction with a positive hepatitis B surface antigen result indicates an early acute HBV infection

CPT Code: 86705

HEPATITIS B IMMUNE STATUS/POST-IMMUNIZATION

Synonyms: Anti-HBs and Anti-HBc

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Thursday

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Request Form: DHEC 1332, Test #222

Special Instructions: Tests includes Anti-HBs and Anti-HBc

Specimen & Volume: 2 ml Whole clotted blood, 1 ml serum or plasma

Container: Red top vacuum tube **See Venipuncture procedure**, **section III**, **if needed**

Storage/Shipping Temperature: Store and ship at room temperature

Specimen must arrive at lab within 5 days of collection. If shipping is delayed more than 5 days after

collection, freeze serum at -20° C and ship on dry ice

Shipping Description: Diagnostic Specimen See packing & shipping instructions, Section IV Rejection Criteria, specific: Improperly stored/shipped or contaminated specimen.

For universal rejections, see Section I.

Methodology: EIA **Add. Information:** NA

CPT Code: 86706 surface antibody; 86704 core antibody

HEPATITIS B SURFACE ANTIGEN

Synonyms: HBsAG

Test Section: Diagnostic Serology, 803-896-0811 **Days Test Performed:** Monday – Thursday **Request Form:** DHEC 1332, Test #225

HEPATITIS B SURFACE ANTIGEN, Cont.

Special Instructions: NA

Specimen & Volume: 2 ml whole clotted blood, or 1 ml serum or plasma **Container:** Red top vacuum tube **See Venipuncture procedure, section III, if needed**

Storage/Shipping Temperature: Store and ship at room temperature; Specimen must arrive at lab within 5 days of collection; If shipping is delayed more than 5 days after collection, freeze

serum at -20° C and ship on dry ice

Shipping Description: Diagnostic Specimen. See packing & shipping instructions, Section IV

Rejection Criteria, specific: Improperly stored/shipped or contaminated specimens

Methodology: EIA **Add. Information:** NA

CPT Code: 87340

HEPATITIS PRENATAL SCREEN - See "Hepatitis B Surface Antigen."

HEPATITIS C, TOTAL ANTIBODY

Synonyms: HCV IgG, HCV total antibody.

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday.

Request Form: DHEC 1332, Test # 224

Special Instructions: For sites requesting HCV RNA if total antibody reactive by EIA, collect blood in a serum separator tube, spin down within 4 hours of collection, and shipcold with cold packs to arrive within 24 hours of collection. Label outside of box HCV Viral Load with indelible marker or sticker that cannot easily be removed.

Specimen & Volume: 0.5 ml whole clotted blood, or 0.250 ml serum or plasma.

Container: Serum separator tube preferred See blood collection procedure for HCV, Section III Storage/Shipping Temperature: Store and ship at room temperature unless HCV RNA requested. Specimen must arrive at lab within 5 days of collection. If shipping is delayed, freeze serum at -20° C and ship on dry ice. See Special Instructions for collection and shipping of HCV RNA samples above. Sample must be shipped according to "Special Instructions".

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen > 5 days old when received (special request specimens); specimen not cold on arrival (project sites); specimen >24 hrs. old when received (project sites); serum separator not used (project sites). For universal rejections, see Section I.

Methodology: NA

Add. Information: Interpretation: A positive HCV total antibody result indicates a past or current HCV infection; all positive HCV results are repeated in duplicate and the results held until the HCV RIBA confirmation assay is performed; The HCV RIBA is performed once a week, usually on Monday

CPT Code: 86803

HEPATITIS C. QUALITATION, RIBA (STRIP IMMUNOBLOT ASAY)

Synonyms: HCV RIBA

Test Section: Diagnostic Serology, 803-896-0811

Davs Test Performed: Once a week, usually on Monday

Request form: DHEC 1332, Test # 224

Special Instructions: Serum Separator tube preferred

Specimen & Volume: One (1) ml Serum or plasma See collection procedure for HCV Section III

Container: Serum separator tube

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs; Specimen must arrive at lab within 24 hours of collection

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV **Rejection Criteria, specific:** Not received within 24 hours or not cold on arrival. For universal rejections, see Section I.

Methodology: Strip Immunoblot Asssay

Add. Information: Interpretation: A positive test result indicates the presence of anti-HCV and past or present HCV infection. An indeterminate test result indicates that anti-HCV may or may not be present and the patient should be retested in 6-12 months. A negative result that was positive by a licensed EIA screening procedure does not exclude the possibility of infection with HCV. Levels of anti-HCV may be undetectable in early infection. The patient should be retested in 6-12 months if he/she is at high risk for hepatitis infection

CPT Code: 86804

HEPATITIS C QUANTITATION BY PCR (RNA)

Synonyms: HCV Viral Load test

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Within 10 working days of collection

Request form: DHEC 1332, Test # 227

Special Instructions: Specimen must be centrifuged within 4 hours of collection

Specimen & Volume: 2 ml. Serum Use serum separator tube, and collect a full 6 ml. of blood.

See blood collection procedure for HCV, section III

Container: Serum separator tube

Storage/Shipping Temperature: Transport on cold packs in a container with return mailing address and the word **HCV** printed on the outside of the container; Use enough cold packs to maintain a temperature between 2°-8 °C during transport; Specimen must arrive at the laboratory **within 24 hours of collection**

Shipping Description: Infectious substance. See packing & shipping instructions, Section IV

Rejection Criteria, specific: Serum separator tube not used, not cold on arrival. For universal rejections, see Section I.

Methodology: Branched DNA (bDNA) Signal amplification nucleic acid probe assay

Add. Information: Used for the rapeutic monitoring of HCV infection

<u>Interpretation:</u> The measurable range for the procedure is 3200 -40,000,000 copies/ml or (615-8,320,000 IU/ML). Specimens within this testing range will be reported as HCV RNA copies/ml = _____IU/ML

HEPATITIS C QUANTITATION BY PCR (RNA), CONT

Specimens less than 3200 copies/ml (615 IU/ML) will be reported as NO HCV RNA detected, less than 3200 copies/ml (less than 615 IU/ML) Specimens above this range will be reported as HCV RNA is greater than 40,000,000 copies/ml (greater than 8,320,000 IU/ML)

CPT Code: 87522

HERPES SIMPLEX CULTURE

Synonyms: Herpes Virus Culture

Test Section: Virology, 803-896-0819 **Days Test Performed:** Monday - Friday **Request Form:** DHEC 1335, Test #250

Special Instructions: DO NOT freeze specimen at -20 °C. See viral culture collection for *H*.

simplex, Section III

Specimen & Volume: Throat swab, NP swab, Cervical/vaginal swabs, Surface lesions or

Tissue; (small piece of fresh, unfixed), CSF

Container: Viral transport media.(available upon request)

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs

Shipping Description: Diagnostic Specimen See Packing and shipping instructions, Section IV **Rejection Criteria, specific:** Calcium alginate swab used; specimen not cold on arrival. For universal rejections, see Section I.

Methodology: Cell Culture
Add. Information: NA

CPT Code: 87252 Culture; 87253 ID

HIV-1 ANTIBODY DETECTION USING ORAL FLUID SAMPLES

Synonyms: Orasure HIV-1

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Batched per volume of samples received, tested at least twice per week.

Request Form: DHEC 1332, Test #230 HIV-1 (EIA Only) **Special Instructions:** Mark Test #15 oral under specimen type

Specimen and Volume: Oral fluid sample collected per instructions found in the Shipping and Collection Section of the Bureau of Laboratories Services Guide. Use the Orasure HIV-1 Oral Specimen Collection Device only. Contact Gwen Pierce at 803-898-0739 for ordering instructions.

Container: HIV-1 Oral Specimen Collection Device

Storage/Shipping Temperature: Store unused Orasure HIV-1 Oral Collection Devices at room temperature(18°C - 25°C, 64°F - 77°F). Exposure to higher temperatures should be avoided. Protect from direct sunlight. Once specimen has been collected, do not expose to temperatures exceeding 37°C (98°F) or direct sunlight. Collected specimens can be stored at 4°C to 37°C (39°F to 98°F) for a maximum of 21 days, including days required for testing. Ship as soon as possible after collection.

Shipping Description: Diagnostic Specimen (See packing and shipping instructions, Section IV) **Rejection Criteria, specific:** Specimen volume not met, clear sample (liquid should be blue on pad), and universal rejections, see Section I.

Methodology: Enzyme Immunoassay (EIA), Western Blot on reactive HIV-1 EIA only.

HIV-1 ANTIBODY DETECTION USING ORAL FLUID SAMPLES (con't)

Additional Information: Interpretation: Repeat reactive specimens are confirmed by Western Blot; recommend repeat testing on all first-time positive patients by serum (if possible) to include CD4 and Viral Load (HIV-1 RNA).

CPT Code: 86701 for EIA, 86689 for Western Blot

HIV-1 PCR QUALITATIVE (DNA)

Synonyms: HIV-1 Proviral DNA Detection

Test Section: Molecular Epidemiology, 803-896-0825

Days Test Performed: Weekly

Request Form: DHEC 1332, Test # 112

Special Instructions: NA

Specimen & Volume: Infants < 18 months old: Collect whole blood in an EDTA pediatric tube

or a heel stick microtainer with EDTA anticoagulant (BD Brand # 365974)

A minimum specimen volume of 0.3 ml is required for testing

Infants≥18 months old and adults: Collect 1.5-2.0 ml EDTA anticoagulant whole blood,

(lavender/purple top vacuum tube) See collection procedure, Section III

Container: EDTA tube or Heel-stick microtainer with EDTA anticoagulant

Storage/ Shipping Temperature: Store and ship at room temperature; Ship using cold packs during hot summer months; **Do not freeze** the specimen; Specimen must arrive at laboratory with 3 days of collection

Shipping Description: Diagnostic specimen. See packing and shipping instructions, section IV.

Rejection Criteria, specific: clotted blood; specimen > than3 days old when received, specimen frozen on arrival. For universal rejections, see Section I.

Methodology: PCR with EIA detection.

Add. Information: If Patient is an infant whose mother is anti-HIV-1 positive, or if Patient is an adult whose anti-HIV-1 tests, i.e., EIA and/or Western Blot, have shown indeterminate or conflicting results; Results are reported either Positive or Negative

CPT Code: 87535

HIV-1 PCR QUANTITATIVE (RNA)

Synonyms: HIV-1 Viral Load test.

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Weekly **Request Form:** DHEC 1332, Test #231

Special Instructions: Label outside of container as HIV(VIRAL LOAD). Make sure label

will not come off

Specimen & Volume: 1.5 to 2.0 ml EDTA anticoagulated plasma **See Venipuncture procedure**, **section III, if needed** If using EDTA vacutainer, separate the plasma from the packed cells within 2 hours of collection by centrifugation for 20 minutes at room temperature; Remove the plasma from the cells using a sterile transfer pipette to a sterile polypropylene transport tube; **Note:** Remove as much of the plasma from the cells as possible without aspirating cells **The assay requires 1.0 ml of plasma**. The PPT separator tube can be shipped after centrifugation without transferring plasma to another tube. Invert tube after centrifugation to insure complete separation of cells from plasma. If cells present in plasma, re-centrifuge before shipping.

HIV-1 PCR OUANTITATIVE (RNA) con't

Container: PPT vaccutainer (supplied by the Bureau of Laboratories call 803-896-0913 to order) or polypropylene tube to which plasma cells have been transferred from the Lavender top (EDTA) vacuum tube

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs; Specimen must arrive at the Laboratory within 24 hours after collection

Shipping Description: Infectious substance. **See packing and shipping instructions, Section IV Rejection Criteria, specific:** Specimen not cold on arrival; whole clotted blood. For universal rejections, see Section I.

Methodology: Branched DNA (bDNA) Nucleic Acid Hybridization with PCR amplification

Add. Information: Therapeutic monitoring of HIV infection

Interpretation: The measurable reportable range for this procedure is 75-500,000 copies/ml plasma; Specimens testing within this range will be reported as the measured number and (in parentheses) as the log 10 value of the measured copy number e.g. 30,000 copies (4.48log 10) the log 10 value will be rounded to the nearest second decimal place. A 0.5 log 10 increase or decrease in the copy number when compared to the patient's previous viral load result is regarded as a significant change Specimens testing above 500,000 will be reported as > 500,000 copies/ ml plasma. Specimens testing below 75 copies/ ml plasma will be reported as "No HIV-1 RNA detected less than 75 copies/ ml plasma"

CPT Code: 87536

HIV-1 SEROLOGY

Synonyms: HIV-1 antibody, Anti-HIV-1

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Friday

Request Form: DHEC 1332, Test #230 HIV-1(EIA only), Test #234 HIV-1 (EIA) and Western Blot

, Test #235 HIV-1 (EIA) and STS(Reagin)

Special Instructions: NA

Specimen & Volume: 1 ml serum or plasma.

Container: Red top vacuum tube **See venipuncture procedure if needed**.

Storage/Shipping Temperature: Store and ship at room temperature; Specimen must arrive at laboratory within 5 days of collection; If shipping is delayed more than 5 days, freeze serum at -20° C and ship on dry ice

Shipping Description: Diagnostic Specimen See Packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I.

Methodology: Enzyme Immunoassay (EIA), Western Blot, and STS Reagin for Syphilis

Add. Information: Interpretation: Repeat reactive specimens are confirmed by Western Blot; Recommend repeat testing on all first-time positive patient results including CD4 and Viral load (HIV-1 RNA)

CPT Code: 86701 for EIA; 86689 for Western Blot, and 86592 for RPR

HIV-1 SEROLOGY using Dried Blood Spots

Synonyms: NA

Test Section: Diagnostic Serology, 803-896-0811 **Days Test Performed:** Monday –Thursday

Request Form: DHEC 1332, Test <u># 230</u> or DHEC 1339

Special Instructions: Write Dried blood spot on form in space above specimen type

Specimen & Volume: Dried Blood spots. Fill all paper circles with blood. Ship within 24 hours

after collection See capillary blood collection by finger stick procedure, Section III

Container: Filter paper attached to requisition form

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV **Rejection Criteria, specific**: Insufficient spots filled, scratched and abraded spots, layered or supersaturated spots. For universal rejections, see Section I.

Methodology: Enzyme Immunoassay (EIA), Western Blot

Add. Information: Repeat reactive specimens are confirmed by Western Blot; Recommend repeat

testing on all first-time positive results

CPT Code: 86701 for EIA; 86689 for Western Blot

HIV-1 SEROLOGICAL MONITORING- See "Lymphocyte Subset"

HOOKWORM - See "Parasite Examination"

HYPOTHYROIDISM - See "Thyroid Panel" for non-neonatal; see "Newborn Screening" for neonatal

INFLUENZA VIRUS CULTURE

Synonyms: Also included in respiratory culture battery

Test Section: Virology, 803-896-0819 **Days Test Performed:** Monday- Friday **Request Form:** DHEC 1335, Test #271

Special Instructions: Collection of a throat washing has been discontinued because of the use of antibiotics in some collection media. Collect swab (do not use alginate swab) and place in transport media; and refrigerate until shipped. Do not allow patient to gargle media

Specimen & Volume: Throat or nasopharyngeal swab See collection procedure for enterovirus or respiratory virus, Section III

Container: Screw capped tube of viral transport media (Available upon request); Keep media refrigerated until used

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Calcium alginate swab used. For universal rejections, see Section I.

Methodology: Cell culture

Add. Information: Submit on patients with symptoms compatible with influenza;

Also see surveillance information below

CPT Code: Tissue Culture, 87252; Identification 87253

INFLUENZA VIRUS A AND B SEROLOGY

Synonyms: NA

Test Section: Virology, 803-896-0819
Days Test Performed: Once/week
Request Form: DHEC 1332, Test #101

Special Instructions: Acute and convalescent specimens required, 2 weeks between specimens

See venipuncture procedure, Section III, if needed

Specimen & Volume: 5 ml Whole clotted blood or 2 ml serum

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: none. For universal rejections, see Section I.

Methodology: Hemagglutination Inhibition (HI)

Add. Information: NA **CPT Code:** 86710 each titer

INFLUENZA SURVEILLANCE

From October to April of each year, the Bureau of Laboratories participates in the World Health Organization's (WHO) Influenza Surveillance Program. Collection kits are provided and there is no charge if submitting throat swabs for the surveillance. Contact the Virology Lab for more information at 803-896-0819.

LEAD ANALYSIS, BLOOD

Synonyms: NA

Test Section: Advanced Analyses, 803-896-0886

Days Test Performed: Monday, Wednesday, Friday

Request Form: DHEC 1332, Test #852

Special Instructions: NA

Specimen & Volume: 200 μl EDTA whole blood from finger stick or heel stick for screening; Venipuncture preferred for confirmation of an elevated level; Minimum acceptable volume is 3 ml for venipuncture; 200 μL for finger stick or heel stick **See blood lead collection procedures, Section III**

Container: Lavender vacuum tube, or lavender Microtainer for finger or heel stick.

Storage/Shipping Temperature: Store and ship at room temperature; Refrigerate specimen if

shipping is delayed.

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Clotted blood, insufficient quantity. See universal rejections Section I.

Methodology: Graphite Furnace Atomic Absorption Spectrometry

Add. Information: <10 μg/dL considered negative for children. Action levels for children and adults printed on results report. Screening levels >10μg/dL require venipuncture confirmation

CPT Code: 83655

LEAD ANALYSIS, ENVIRONMENTAL SAMPLES

Synonyms: NA

Test Section: Advanced Analyses, 803-896-0886

Days Test Performed: Monday- Thursday

Request Form: DHEC 1332, Test #854

Special Instructions: NA

Specimen & Volume: 1 Tablespoon Paint chips, 2 Tablespoons soil, or 100 ml water

Container: Zip-lock bag for paint and soil. Plastic container for water

Storage & Shipping Temperature: Store and ship at room temperature **Shipping Description:** Environmental sample. Does not require special packaging

Rejection Criteria, specific: NA

Methodology: Flame Atomic Absorption Spectrometry

Add. Information: Contact DHEC Environmental Health 896-0655 for interpretation of results

CPT Code: NA

LEGIONELLA CULTURE

Synonyms: Legionnaire's disease; Legionella culture **Test Section:** Bacteriology/Parasitology, 803-896-0805

Days Test Performed: Monday – Friday **Request Form:** DHEC 1335, Test #510

Special Instructions: Note: urine antigen test is not available at the Bureau of Laboratories

LEGIONELLA CULTURE, CONT

Specimen & Volume: 1-2 ml Sputum, Bronchial washing, pleural fluid, or other body fluids,

lung tissue, bacterial isolate

Container: Sterile leak-proof container

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs; Specimen must arrive at laboratory within 48 hours of collection; If shipping is delayed for more than 48 hours,

freeze at -20 C and ship on dry ice

Shipping Description: Diagnostic Specimen; Isolate is considered Infectious substance See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen not cold on arrival; for universal rejections, see Sect. I.

Methodology: Conventional culture and biochemical methods

Add. Information: NA

CPT Code: Culture – 87070, culture; 87077 ID

LEGIONELLA FA

Synonyms: NA

Test Section: Bacteriology/Parasitology, 803-896-0805

Days Test Performed : Monday-Friday **Request Form:** DHEC 1335, Test #513

Special Instructions: FA test is screening only; culture is recommended; test #510 will be performed on all specimens for FA that are appropriate for culture.

Specimen & Volume: Fresh lung tissue imprints; scrapings of formalin fixed tissue or lower respiratory tract fluids/sputum; TTA; bronchial washings; pleural fluid; smears on slides(submit at least 2 separate slides), or culture isolate.

Container: Sterile, leak-proof container; crush-proof slide holder; or screw-cap tube containing agar medium that will support growth of isolate.

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen; see packing and shipping instructions Section IV.

Rejection Criteria, specific: None. For universal rejections, see Section I.

Methodology: FA Stain Add. Information: NA CPT Code: 87206

LEGIONELLA SEROLOGY

Synonyms: NA

Test Section: Virology, 803-896-0819 **Days Test Performed:** Weekly

Request Form: DHEC 1332, Test #023

Special Instructions: Paired specimen required and should be taken 3-4 weeks apart

Specimen & Volume: 5 ml whole clotted blood or 2 ml serum **See venipuncture procedure**,

Section III, if needed

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

LEGIONELLA SEROLOGY, cont.

Rejection Criteria, specific: Only one specimen received. For universal rejections,

see Section I.

Methodology: IFA

Add. Information: Interpretation: titer <1:128 is considered negative; a four-fold rise in titer(at

least 1:512) from acute to convalescent is considered positive.

CPT Code: 86713

LEISHMANIASIS - See "Parasite Serology"

LEPTOSPIROSIS CULTURE

Synonyms: NA

Test Section: CDC Leptospira Lab 404-639-3905

Days Test Performed: Referred to CDC

Request Form: CDC Form

Special Instructions: Blood specimens should be collected during the first week of symptoms. After the first week of symptoms, collect a mid-stream, clean catch urine specimen; Five (5) tubes of PLM media should be requested from CDC prior to sample collection

Specimen & Volume: 1 ml of heparinized blood or clean catch urine; Collect urine in clean container; Inoculate immediately; Put two (2) drops of blood or urine in each tube of medium; Avoid agitation of the blood sample because free hemoglobin kills Leptospira

Container: Screw capped tubes of PLM media

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Blood specimen collected after first week of illness; specimen not

inoculated into PLM media prior to transport. For universal rejections, see Section I.

Methodology: Conventional culture

Add. Information: Serology test is more sensitive and has a shorter turnaround time

CPT Code: 87040 (blood culture); 87088 (urine culture), 87077, ID.

LYME DISEASE

Synonyms: Borrelia Antibodies

Test Section: Virology, 803-896-0819 **Days Test Performed:** Weekly

Request Form: DHEC 1332, Test # 024

Special Instructions: NA

Specimen & Volume: 5 ml whole blood or 2 ml; Serum

Container: Red- top vaccutainer See Venipuncture procedure, Section III, if needed

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For universal rejections, see Section I.

Methodology: EIA

Add. Information: All positive EIA results are confirmed by western blot

CPT Code: 86618

LYMPHOCYTE SUBSET

Synonyms: CD4; T4 lymphocytes

Test Section: Clinical Labs section, Hematology Unit, 803-896-0954

Days Test Performed: Monday - Friday **Request Form:** DHEC 1332, Test #780

Special Instructions: Specimen must be less than 24 hours old when tested by laboratory **Specimen & Volume:** 5-7 ml EDTA anticoagulated whole blood Mix well but gently

Container: Lavender top (EDTA) vacuum tube See Venipuncture procedure, Section III, if needed Storage/Shipping Temperature: Store and ship at room temperature. Do not refrigerate. Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Specimen more than 24 hours old upon arrival, specimen

clotted, Specimen received cold or frozen. For universal rejections, see Section I.

Methodology: Laser Flow cytometry

Add. Information: Used To evaluate HIV status

Reference value: CD4 cells 34-59%, CD4/CD8 ratio 0.9-3.1, results highly variable during

progression of disease NOTE: Lymphocyte subset includes CBC results

CPT Code: 86360, CD4/CD8 profile; 85025, CBC

MALARIA SMEAR

Synonyms: Giemsa Stain; Blood Parasite

Test Section: Bacteriology/ Parasitology 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test # 404

Special Instructions: Prepare 2-3 thick and thin smears immediately after collection

Specimen & Volume: EDTA anticoagulant whole Blood

Container: Slides and EDTA Tube of blood for referral if necessary

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions Section IV **Rejection Criteria**, specific: Clotted blood smears made from EDTA blood > 1 hr old;

Blood smears> 3 days old. For Universal rejections, see Section I. **Methodology:** Microscopic examination of Giemsa stained smear

Add. Information: Used to detect blood parasites such as: malaria, microfilaria

CPT Code: 87207

MCADD (Medium chain Acyl Co-A Dehydrogenase Deficiency) - See Newborn Screening

MEASLES SEROLOGY See Rubeola and Rubella Serology

MHA-TP - See TP-PA

MICROSPORIDIUM STAIN

Synonyms: Chromotrope 2R Stain for microsporidium, Enterocytozoan Stain

Test Section: Bacteriology/Parasitology, 803-896-0805 **Days Test Performed:** Monday - Friday, as requested

Request Form: DHEC 1335, Test # 410

Special Instructions: Do not concentrate specimen

Specimen & Volume: 1 ml fresh stool less than 1 hour old preserved in 10% formalin; duodenal

aspirates in 10% formalin; urine sediment, sputum, corneal scrapings, nasal smears

(please submit at least 2 thin smears)

Container: Screw-capped leak proof container/tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: PVA preserved stool, plastic or paraffin-embedded tissue. For

Universal rejections, see Section I.

Methodology: Chromotrope 2R Stain/light microscopy

Add. Information: Diagnosis of Microsporidian infection by detection of spores

CPT Code: 87207

MITES - See "Scabies"

MUMPS VIRUS CULTURE

Synonyms: also see respiratory viral culture **Test Section:** Virology, 803-896-0819 **Days Test Performed:** Monday - Friday **Request Form:** DHEC 1335, Test #270

Special Instructions: NA

Specimen & Volume:, Urine preferred, Throat swab, CSF See throat swab collection, Section III, if

needed.

Container: No transport media needed for urine or CSF. Use sterile leakproof container. Screw capped tube of viral transport media (available upon request) for throat swab.

Storage/Shipping Temperature: Store in refrigerator; Ship with cold packs. If shipping is delayed more than 48 hours, freeze at -70 C and ship on dry ice

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Use of calcium alginate swab for throat specimen; specimen not cold on arrival. For Universal rejections, see Section I.

Methodology: Cell Culture **Add. Information:** NA

CPT Code: Culture, 87252; Identification 87253

MUMPS VIRUS SEROLOGY

Synonyms: NA

Test Section: Virology, 803-896-0819 **Days Test Performed:** Once/week

Request Form: DHEC 1332, Test #135 Mumps IgG (single specimen)

Special Instructions: NA

Specimen & Volume: 2 ml. whole clotted blood or 1 ml. serum See Venipuncture procedure,

Section III, if needed

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: EIA

Add. Information: Immune status reported as positive, negative or equivocal

CPT Code: 86735

MURINE TYPHUS SEROLOGY - See "Rickettsial Serology"

MYCOBACTERIAL CULTURE, BLOOD

Synonyms: TB, AFB

Test Section: Mycobacteriology (TB), 803-896-0828

Days Test Performed: Monday-Friday **Request Form:** DHEC 1335, Test #601

Special Instructions: Use Bactec 13A Vial(1) Clean septum of 13A vial with 70% alcohol; (2) Use good aseptic technique to cleanse arm; (3) Aseptically draw 4 to 5 ml blood and inject into 13A vial (4) Clean top of vial with 70% alcohol, cover top with tape and mail in mailer provided **Specimen & Volume:** 4-5 ml whole Blood **See Venipuncture procedure, Section III, if needed**

Container: Bactec 13A Vial (Call Lab for container, 896-0828)

Storage/Shipping Temperature: Store and ship at room temperature; Incubate at 37 ° C if shipping is delayed over 24 hours

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV **Rejection Criteria**, specific: Specimen >5 day old. For Universal rejections, see Section I.

Methodology: Bactec 460 system, HPLC, Gen-Probe

Add. Information: NA

CPT Code: 87116(Culture). For ID, 87149(Gen-Probe) and 87143-(HPLC)

MYCOBACTERIAL CULTURE, Other than Blood

Synonyms: AFB, TB

Test Section: Mycobacteriology (TB), 803-896-0828

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #601

Special Instructions: NA

Specimen & Volume: 5-10 ml Sputum, and other body fluids; 10 ml urine or gastric washings, Walnut sized portion of feces or 10 ml liquid stool **See mycobacterium culture collection procedure**, **Section III**

Container: Screw capped 50 ml polypropylene conical tube

Storage/Shipping Temperature: Store and ship Sputum at room temperature.

If shipping is delayed more than 24 hours, store in refrigerator. Store Urine in refrigerator and ship cold with cold packs.

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV **Rejection Criteria, specific:** Specimen > 5 days old when received (Sputum and Urine). For Universal rejections, see Section I.

Methodology: Conventional culture methods, Gen-probe and HPLC for ID

Add. Information: NA

CPT Code: 87015 for conc; 87116 for culture; For ID, use 87149 -Gen-Probe & 87143-HPLC

MYCOBACTERIAL CULTURE, REFERRED FOR IDENTIFICATION

Synonyms: AFB, TB

Test Section: Mycobacteriology (TB), 803-896-0828

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test # 602

Special Instructions:

Specimen & Volume: Send only pure culture with sufficient growth to perform test

Container: LJ slant preferred

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Infectious substance See packing and shipping instructions, Section IV Rejection Criteria, specific: Contaminated culture, non-viable organism. For Universal

rejections, see Section I.

Methodology: HPLC, Gen-Probe

Add. Information: NA

CPT Code: 87149 GenProbe and 87143- HPLC

MYCOBACTERIA ANTIBIOTIC SUSCEPTIBILITY

Synonyms: Sensitivity Testing

Test Section: Mycobacteriology (TB), 803-896-0828

Days Test Performed: Weekly on new TB isolates and by request on previously positive patients

Request Form: DHEC 1335, Test # 604

Special Instructions: Call Laboratory for drugs other than INH, Ethambutol, Rifampin,

Streptomycin and Pyrazinamide **Specimen & Volume:** NA

Container: NA.

Storage/Shipping Temperature. NA.

Shipping Description: NA

Rejection Criteria, specific: None. For universal rejections, see Section I.

Methodology: Bac-Tec, conventional

Add. Information: NA

CPT Code: 87190 for Bac-Tec, 87184 for conventional disk method

MYCOPLASMA HOMINIS/UREAPLASMA CULTURE (GENITAL)

Synonyms: *M. hominis and Ureaplasma*Test Section: Virology, 803-896-0819
Days Test Performed: Monday-Friday
Request Form: DHEC 1335, Test #272

Special Instructions: Please call Virology prior to sending, as special transport medium is

required See mycoplasma/ureaplasma cuture collection procedure, Section III

Specimen & Volume: Vaginal swab, cervical swab, urethral swab, urine, endometrial washings,

and placenta

Container: Screw capped tube of mycoplasma hominis and ureaplasma transport media

Storage/Shipping Temperature: *If M. hominis* is suspected, Store in refrigerator and ship with cold packs, if specimen will reach the laboratory within 6 hours; If shipping is delayed, freeze at -70° and ship on dry ice; If *Ureaplasma* is suspected, store in refrigerator and ship with cold packs; Specimen must arrive at laboratory within 48 hours of collection

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV **Rejection Criteria**, specific: Cotton swab with wooden shaft used for collection; Incorrect collection media used; specimen not received within stated time; specimen not cold on arrival. For Universal rejections, see Section I.

Methodology: Culture **Add. Information:** NA

CPT Code: Culture, 87109; Identification, 87253

MYCOPLASMA PNEUMONIAE CULTURE (RESPIRATORY)

Synonyms: Mycoplasma pneumoniae Test Section: Virology, 803-896-0819 Days Test Performed: Monday-Friday Request Form: DHEC 1335, Test #272

Special Instructions: DO NOT use calcium alginate swab for collection Place swab in viral

transport media after collection.

Specimen & Volume: Throat swab or Bronchial washing. See viral respiratory culture collection

procedure, Section III

Container: Screw capped tube of viral transport media

Storage/Shipping Temperature: Store in refrigerator; Ship with cold packs; Specimen must

arrive at laboratory within 48 hours of collection

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen more than 48 hrs old when received; Calcium alginate

swab used. For universal rejections, see Section I.

Methodology: Culture Add. Information: NA

CPT Code: Culture, 87109; Identification, 87253

NAEGLERIA CULTURE - See "Amoebae Culture"

NEWBORN SCREENING PANEL

Synonyms: NA; <u>Tests include</u>: Amino Acid profile (including PKU), Galactosemia (GAO & GALT), T4 and TSH for Congenital Hypothyroidism (CH), Congenital Adrenal Hyperplasia (CAH), Hemoglobinopathies (Sickle variants, etc.), Acylcarnitine(including MCADD), Biotinidase Deficiency and Immuno Reactive Trypsin (IRT) for Cystic fibrosis.

Test Section: Newborn Screening, 803-896-0874

Days Test Performed: Monday - Friday

Request Form: DHEC # 1327

Special Instructions: See capillary blood collection by heel stick, Section III

Specimen & Volume: Whole bloodspots on filter paper; Fill all circles with blood

Container: Special Filter paper attached to request form and preaddressed mailing envelope

Storage/Shipping Temperature: Allow blood to dry 4hrs or overnight before packing; Store and ship at room temperature; Ship within 24 hours of collection; Do not mail in plastic biohazard bags

Shipping Description: Diagnostic Specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Scratched and abraded, contaminated, layered, or super- saturated spots. For Universal rejections, see Section I.

Methodology: T4 Thyroid, TSH Thyroid, 17-OHP(CAH), IRT(Cystic Fibrosis), GALT and TGAL(GAL)-- Fluoroimmunoassay (FIA); Hemoglobinopathies -- Isoelectric Focusing (IEF), and High Pressure Liquid Chromatography(HPLC); Amino Acid Profile, and Acylcarnitines--Tandem Mass spectrophotometry; and Biotinidase—UV Analysis

Add. Information: Interpretation: All results will be reported to the hospital, clinic, or institution and the attending physician (2 separate copies); All tests except Hemoglobinopathies are reported as normal or Abnormal. If abnormal, the value is also given on the report or in a follow up letter. Hemoglobins are reported as normal or with the appropriate hemoglobinopathy identified.

1. Amino Acid Profile:

If any amino acid level is outside normal limits, a quantitative result is given.

Abnormal screen values are as follows:

PKU- Phenylalanine (PHE) level of ≥3 mg/dL or 180 µM.

Homocystinuria Methionine (MET) level of ≥100 µ

Maple Syrup Urine Disease (MSUD) Valine (VAL) level of ≥ 275 µM

And leucine (Leu) and isoleucine (ILE) level of $\geq 375 \, \mu M$.

Citrullinemia CIT level of ≥ 76 µM.

Argininosuccinic Aciduria- CIT ≥ 76 µM

For PKU. If the infant is diagnosed as having phenylketonuria, the infant should be provided a low phenylalanine diet. Repeat blood examinations can be performed as necessary to assist the physician in maintaining the phenylalanine level within prescribed limits

2. Congenital Hypothyroid (CH) Screen:

All infants receive a T4 (Thyroxine) and a TSH (Thyroid Stimulating Hormone) screening test.. A T4 value of $\leq 7 \,\mu\text{g/dL}$ is abnormal for infants $\leq 7 \,\text{days}$ old.

A T4 value of $\leq 4\mu g/dL$ is abnormal for infants ≥ 8 days old.

A TSH value of \geq 22 μ IU/mL is abnormal for all infants, regardless of age.

NEWBORN SCREENING PANEL, Cont.

3. Congenital Adrenal Hyperplasia (CAH) Screen:

17-OH-progesterone value of \geq 40 ng/ml or for infants with a birth weight of \geq 2500 grams are reported as Abnormal

17-OH-progesterone value of \geq 65 ng/ml for infants with a birth weight of < 2500 grams are reported as Abnormal..

4. Galactosemia (GAO) Screen:

All infants receive a total Galactose and galactose-1-phosphate uridyl transferase (GALT) enzyme screen tests. A Galactose value ≥ 10 mg/dL is considered Abnormal. GALT is reported as Normal or Deficient (abnormal). A GALT level ≤ 60 μ M is considered deficient.

5. Hemoglobinopathy (Hb) Screen:

Results are reported as normal hemoglobin (Hb FA or Hb AF) or as an interpretative diagnosis for abnormal Hemoglobins. (e.g. Hb FAS, FAC FS) **Please note that this test does not detect all Thalassemias or Hemoglobins.**

<u>HbA2 and S Quantitation (when whole blood is received)</u>: Results are reported as a percentage hemoglobin. HbA2 percentage \geq 3.5% is reported as abnormal.

6. Acylcarnitines Profile

This profile identifies numerous inborn errors of fattyacid oxidation.

Results are reported as Normal or Abnormal. If all or any acylcarnitines are outside (greater than the cutoff) normal limit, a quantitative result will be given along with the abnormal cutoff level.

Medium Chain Acyl co-A Dehydrogenase Deficiency (MCADD)

The C8.carnitine, and the C8/C10 ratio, must be elevated for the test to be reported as a positive screening for MCADD. Elevated levels of one or more, but not all, of the measured carnitines will be reported as "may be indicative of a fatty acid oxidation disorder"

Abnormal Acylcarnitine cutoff levels

Primary Markers

C8 (Octanoyl carnitine) $\geq 0.60 \text{ uM}$ C8/C10 ratio ≥ 3.0

Secondary Markers

C6 (Hexanoyl carnitine) $\geq 0.52 \text{ uM}$ C10 (Decanoyl carnitine) $\geq 0.38 \text{ uM}$ C10:1 (Decenoyl carnitine) $\geq 0.25 \text{ uM}$

Note: Acylcarnitine levels drop precipitously over the first few weeks of life in both normal and affected infants, with affected infants values remaining in the abnormal range. A decrease in measured Acylcarnitine levels in an infant with MCADD over a period of time should not be interpreted as condition improvement. The infant has MCADD

Short chain Acyl co-A Dehydrogenase Deficiency (SCADD)

Abnormal Acylcarnitine cutoff levels

C4 (butyryl carnitine) $\geq 1.86 \mu M$

Long Chain 3-)H Acyl co-A Dehyddrogenase Deficiency (LCHADD)or Trifunctional Protein Deficiency (TFP)

Abnormal Acylcarnitine cutoff levels

Primary Marker

C16-OH (30OH palmitoyl carnitine).≥ 1.15 µM

NEWBORN SCREENING PANEL, Cont.

Trifunctional Protein Deficiency (TFP),(cont)

Secondary Markers

C14:1 (Tetradecenoyl carnitine) $\geq 0.64 \mu M$ C16 (Palmitoyl carnitine) $\geq 8.91 \mu M$ C18:1 (oleyl carnitine) $\geq 3.54 \mu M$ C18:1-OH (3-OH Oleyl carnitine) $\geq 0.11 \mu M$

Very Long Chain Acyl co-A Dehyddrogenase Deficiency (VLCADD)

Abnormal Acycarnitine cutoff levels

Primary Markers

C14:1 (Tetradecenoyl Carnitine) ≥ 0.64 µM

C14:1/C12:1 ratio ≥3

Secondary Markers

C14 (Tetradecanoyl carnitine) $\geq 0.84 \mu M$ C16 (Palmitoyl carnitine) $\geq 8.91 \mu M$

C18:1 (Oleyl carnitine) $\geq 3.54 \,\mu\text{M}$

Glutaric Aciduria Type II (GAII)

Abnormal Acycarnitine cutoff levels

Primary Markers

C4 (Butyryl carnitine) $\geq 1.86 \mu M$ C5 (Isovaleryl carnitine) $\geq 1.00 \mu M$

Secondary Markers

The Markers

C6 (Hexanoyl carnitine) $\geq 0.52 \text{ uM}$ C8 (Octanoyl carnitine) $\geq 0.60 \text{ uM}$ C10 (Decanoyl carnitine) $\geq 0.38 \text{ uM}$ C16 ((Palmitoyl carnitine) $\geq 8.91 \text{ uM}$ C18:1 (oleyl carnitine) $\geq 3.54 \text{ µM}$

Carnitine Palmitoyl Transferase II Deficiency (CPT II)

Abnormal Acycarnitine cutoff levels

C16 ((Palmitoyl carnitine ≥ 8.91 uM

C18:1 (oleyl carnitine) $\geq 3.54 \,\mu\text{M}$

Carnitine/Acylcarnitine Translocase Deficiency (CACT)

Abnormal Acycarnitine cutoff levels

C16 (palmitoyl carnitine $\geq 8.91 \text{ uM}$ C18:1 (oleyl carnitine) $\geq 3.54 \text{ }\mu\text{M}$

7. <u>Biotinidase Deficiency</u>

A Biotinidase level of ≤ 10 ERU(Enzyme Response Units) is considered deficient

8. Cystic Fibrosis (CF)

Abnormal result levels

An IRT (immunoreactive trypsinogen) level of ≥ 105 ng/mL in initial specimen

An IRT level of ≥ 70 ng/mL in subsequent specimens

CPT CODES: Amino Acid Profile-83139, T4-84437; TSH-84443; CAH-83498,

Galactosemia-82760, 82775; Hemoglobinopathies 83020, Acylcarnitines 82017, IRT for Cystic Fibrosis 83516

NOROVIRUS DETECTION BY PCR

Synonyms: Norwalk or Norovirus PCR

Test Section: Molecular Epidemiology 803-896-0825

Days Test Performed: Weekly

Request Form: DHEC 1335, Test #114

Special Instructions: Batch stool specimens if possible. Rectal swabs are of insignificant value

because they contain too little nucleic acid for amplification

Specimen & Volume: 1 ml fresh diarrheal stool specimen. Specimens collected within 48-72 hours of onset of symptoms are best; Specimens collected within 7 days of onset of symptoms will be accepted

Container: Sterile screw capped 50 ml.polypropylene conical tube or Enteric Kit.

Storage/Shipping Temperature: Store in refrigerator; Ship with cold packs

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen not cold on arrival; Specimen more than 7 days old when received. For Universal rejections, see Section I.

Methodology: Reverse transcriptase polymerase chain reaction (RT-PCR)

Add. Information Used to detect the presence of Norwalk-like virus (RNA).

RT-PCR results are positive or negative for the presence of Norwalk-like viruses (NLV)

CPT Code: 83890 extraction; 83894Gel electrophoresis; 83898 amplification; 83902 Reverse transcriptase

OVA AND PARASITES EXAMINATION(O & P)-See "Parasite Examination, General"

PAP SMEAR /BREAST SMEAR CYTOLOGY

Available only to DHEC county health department clinics

Synonyms: Paps smear, Breast smear
Test Section: Cytology, 803-896-0892
Days Test Performed: Monday-Friday
Request form: DHEC 1362, Test # 65000

Special Instructions: NA

Specimen & Volume: Fixed Cervical or vaginal smear, or breast smear See collection procedures,

Section III

Container: Microscope slide

Storage/Shipping Temperature:. Slides may be stored indefinitely when spray-fixed;

Store and ship at room temperature Use slide mailer.

Shipping Description: Fixed slides are considered non-hazardous and do not require special

precautions for transport See packing and mailing instructions, Section IV

Rejection Criteria, specific: Air drying of slide. For Universal rejections, see Section I.

Methodology: Microscopic observation of stained smears

Use/Add. Information: <u>Interpretation:</u> Findings are reported using the Bethesda System; Screening for presence of atypical, pre-neoplastic and neoplastic cells: Screening for presence of certain

types of genital infections; evaluation of hormonal function (vaginal smears only) **CPT Code:** Screen 88164; physician's interpretation 88141

PARAINFLUENZA VIRUS CULTURE- See respiratory viral culture

PARASITE EXAMINATION, GENERAL (O & P)

Synonyms: Ova and parasites, (O & P)

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #401

Special Instructions: NA

Specimen & Volume: "Walnut" sized Stool, or 2 Tbsp liquid stool preserved in 10% formalin, SAF (sodium-acetate-acetic acid formalin), MIF (merthiolate-iodine-formalin) or PVA Note: Submit

liquid or soft specimens in PVA for detection of trophozoites See collection procedure, Section III

Container: Leak proof screw cap tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen contaminated with urine or water, laxatives or barium; specimens covered in fungal growth; specimens that appear hard and desiccated; specimens more than 4 days old. For Universal rejections, see Section I.

Methodology: Microscopic exam of concentrate. FA for Giardia/ Cryptosporidia **Add. Information:** Detection of protozoan cysts, helminth eggs and larvae

CPT Code: 87177, Microscopic exam; 87206, FA

PARASITE EXAMINATION, STAINS,-See Cryptosporodium and Trichrome stains

PARASITE EXAMINATION, BLOOD PARASITES - See "Malaria Smear"

PARASITE EXAMINATION, ID OF PROGLOTTID OR WORM

Synonyms: NA

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #405

Special Instructions: Submit in 10% formalin or alcohol if formalin not available

Specimen & Volume: Proglottid or worm

Container: Leak-proof screw cap tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, **specific:** NA. For Universal rejections, see Section I.

Methodology: Visual or microscopic Examination of specimen

Add. Information: NA

CPT Code: 87168

PARASITE EXAMINATION, PINWORM - See "Pinworm Exam"

PARASITE SEROLOGY

Synonyms: NA; Test include: Chagas disease, cysticercosis, echinococcosis, leishmaniasis, malaria,

schistosomiasis, trichinosis, visceral larva migrans (Toxocara) Toxoplasmosis; For additional information call 803-896-0805

Test Section: Referred to Centers for Disease Control and Prevention (CDC) for testing

Days Test Performed: NA

Request Form: CDC Specimen Referral Form 50.34 Rev. 8-84

Special Instructions: NA

Specimen & Volume: 2 ml Whole clotted blood or serum

Container: Red top vacuum tube See Venipuncture procedure, Section III if needed

Storage/Shipping Temperature: NA

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None For Universal rejections see Section I.

Methodology: NA **Add. Information:** NA

CPT Code: NA

PARVOVIRUS IgG/IgM SEROLOGY

Synonyms: NA

Test Section: Virology, 803-896-0819 **Days Test Performed:** Weekly

Request Form: DHEC 1332, Test #257

Special Instructions: Single specimen only

Specimen & Volume: 5 ml whole blood or 2 ml serum See Venipuncture procedure, Section III

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: IFA

Add. Information: Interpretation: Positive or negative for Parvovirus

CPT Code: 86747 each immunoglobulin

PINWORM EXAMINATION

Synonyms: Enterobius vermicularis, Cellophane tape prep, Scotch tape prep

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #403

Special Instructions: Use <u>clear</u> cellophane tape, collect first thing in the morning

Specimen & Volume: E. vermicularis ova from the perianal area See pinworm prep collection

procedure, Section III

Container: Microscope slide with collection tape

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

PINWORM EXAMINATION, CONT

Rejection Criteria: Use of frosted cellophane tape, stool specimen. For Universal rejections, see

Section I.

Methodology: Microscopic examination for detection of pinworm eggs and adult worms

Add. Information: NA

CPT Code: 87172

PKU - See "Newborn Screening"

POLIOMYELITIS - See Enterovirus culture

PREMARITAL PROFILE FOR OUT OF STATE LICENSES

NOTE: No premarital testing is required for South Carolina marriage license

Synonyms: NA

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Monday-Friday

Request Form: DHEC 1332 Rubella IgG(Test #005), Syphilis & HIV (Test #235) Under "Reason

for Test/Visit", check Premarital and indicate state where marriage will take place

Special Instructions: Tests vary according to specific state (**See table 4, Section I for listing**) **Specimen & Volume:** 2 ml Whole blood or serum **See venipuncture procedure, Section III**

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: NA. For Universal rejections, see Section I.

Methodology: EIA- Rubella and HIV; RPR- Syphilis

Add. Information:

CPT Code: Syphilis - 86592; Rubella – 86762; HIV-86701

PRENATAL PANEL

Available only to DHEC clinics

Synonyms: Initial screen includes Syphilis, Rubella, Hep B surface antigen, ABO, Rh and AB

screen, HIV; CBC included only if requested

Test Section: Diagnostic Serology 803-896-0811 and Clinical labs sections 803-896-0954

Days Test Performed: Monday - Friday **Request Form:** DHEC 1332, Test #030

Special Instructions: For AB screen- separate serum from clot if transport time > 48 hours; if repeat testing is required, mark individual test

Specimen & Volume: 2 x 7 ml whole blood **AND** 7 ml EDTA anticoagulated whole blood

Container: 2 red-top and 1 lavender top vacuum tubes; Do **not** use serum separator

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Serum separator tube used for EDTA collection. For Universal

rejections, see Section I.

PRENATAL PANEL, CONT

Methodology: EIA- HBsAg, HIV-1, and Rubella.; RPR-Syphilis; Hemagglutination-ABO; and Rh;

Antiglobulin test- AB Screen; Automated cell counter if CBC requested

Add. Information: Reference values are printed on results report.

CPT Code: 80055 for panel of tests

PSEUDOMEMBRANOUS COLITIS- See C. difficule

PVA PRESERVED FECAL SPECIMEN - See "Trichrome Stain"

RABIES EXAMINATION

NOTE: The Bureau of Laboratories is the only laboratory in S.C. which performs tests for rabies in animals. CDC performs all testing on human subjects. There is a special holiday and weekend on-call system for consultation and emergency testing that can be accessed by calling the main laboratory number, 896-0800.

Synonyms: NA

Test Section: - Virology, 803-896-0819

Days Test Performed: Monday- Saturday; Sunday and holidays if human exposure involved

Request Form: DHEC 1308, Test #26000

Special Instructions: Contact the local county health department for information on specimen collection and shipping instructions; **Confirmation is a postmortem procedure**; Because standard procedure currently requires the examination of brain tissue, the suspect animal must either be sacrificed or have died before the examination can be performed; All county health departments maintain containers appropriate for shipping specimens for examination, information on the management of animals suspected of being rabid, and to obtain vaccine for persons exposed to a rabid animal after consultation with the state epidemiologist

Specimen & Volume: Brain tissue Container: ship whole animal head

Storage/Shipping Temperature: Keep cold; See special instructions above **Shipping Description:** Diagnostic specimen; See special instructions above

Rejection Criteria, specific: No brain tissue or tissue decomposed or grossly contaminated. For Universal rejections, see Section I.

Methodology: Fluorescent Antibody (FA)

Add. Information: Reported as positive or negative. All positive reports are called directly to the county health department, or after regular working hours, to the county environmentalist who submitted the specimen

CPT Code: NA

RESPIRATORY VIRUS CULTURE

Synonyms: Battery of tests includes culture for Influenza A & B, Parainfluenza I, II, II,

Adenovirus and Respiratory Synctial (RSV) from a single specimen.

Test Section: Virology, 803-896-0819 **Days Test Performed:** Monday - Friday **Request Form:** DHEC 1335, Test #270

Special Instructions: NA

RESPIRATORY VIRUS CULTURE, CONT

Specimen & Volume: Throat swab See respiratory virus culture collection procedure, Section III

Container: Screw capped tube of viral transport media (Available upon request)

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs within 24-48

hours. If shipping is delayed more than 48 hours, freeze at -70°C and ship on dry ice

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen not cold on arrival; calcium alginate swab used for

collection. For Universal rejections, see Section I.

Methodology: Culture **Add. Information:** NA

CPT Code: Culture, 87252; Identification, 87253

RH FACTOR- See Prenatal Testing

RICKETTSIAL SEROLOGY (RMSF, MT)

Synonyms: Rocky Mt. Spotted Fever / Murine Typhus serology

Test Section: Virology, 803-896-0819

Days Test Performed: Monday, Wednesday, and Friday

Request Form: DHEC 1332, Test # 021 (RMSF) and #028 (MT)

Special Instructions: Acute & convalescent sera needed, convalescent should be taken three

weeks after onset of disease

Specimen & Volume: 5 ml whole blood or l ml serum **See Venipuncture procedure, Section**

III, if needed

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: NA. For Universal rejections, see Section I.

Methodology: Indirect Fluorescent Antibody (IFA)

Add. Information: <u>Interpretation:</u> Single titers of 1:64 are considered borderline; Titers may be low or negative (1:64 or lower) if specimen was collected earlier than 10 days after onset; A 4-fold rise

between paired sera is diagnostically significant

CPT Code: 86757 each titer

RPR - See "Syphilis Serology (STS)"

RUBELLA SEROLOGY- IgG and IgM

Synonyms: German measles antibody, rubella immune screen, rubella IgG., and IgM

Test Section: IgG-Chemistry 803-896-0891; IgM- Virology, 803-896-0819

Days Test Performed: Monday - Friday

Request Form: DHEC 1332 - Test # 006 for IgM, Test #005 for IgG

Special Instruction: Call prior to sending specimen for IgM-Virology, 896-0819

Rubella IgG does not require calling

Specimen & Volume: 2 ml whole clotted blood, or 1 ml serum or plasma

Container: Red top vacuum tube. See Venipuncture procedure, Section III, if needed

RUBELLA SEROLOGY- IgG and IgM, CONT

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: EIA **Add. Information:** NA

CPT Code: 86762 (each immunoglobulin)

RUBEOLA VIRUS SEROLOGY-IMMUNE STATUS

Synonyms: Measles IgG

Test Section: Virology, 803-896-0819

Days Test Performed: Once/Week

Request Form: DHEC 1332, Test #132

Special Instructions: NA

Specimen & Volume: 5 ml whole clotted blood or 2 ml serum

Container: Red top vacuum tube See Venipuncture procedure, Section III, if needed Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: EIA

Add. Information: Used to determine immune status of patient

CPT Code: 86765

RUBEOLA SEROLOGY -DIAGNOSTIC

Synonyms: Measles IgM

Test Section: Virology, 803-896-0819 **Days Test Performed:** Upon request **Request Form:** DHEC 1332, Test #111

Special Instructions: Call Virology (896-0819) prior to sending specimen

Specimen & Volume : 5 ml whole clotted blood or 2 ml serum

Container: Red top vacuum tube See Venipuncture procedure, section III, if needed Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: EIA

Add. Information: Used in Diagnosis of measles and used during possible outbreaks; IgM

antibodies usually appear 3-5 days after onset of rash

CPT Code: 86765

SARS-(SEVERE ACUTE RESPIRATORY SYNDROME)

Note: By special arrangement only. Contact DHEC District Epidemiology coordinator for information on meeting case definition criteria before collecting or submitting specimen.

Synonyms: SARS-CoV, SARS Coronavirus

Test Section: Molecular Epidemiology section, 803-896-0825

Days Test Performed: As required **Request Form:** DHEC 1335 Test #123

Special Instructions: Use Dacron swab only. DO NOT use Calcium Alginate swab or swab with

wooden shaft.

Specimen & Volume: One Nasal or oropharyngeal swab, tracheal aspirate

Container: Submit swab dry in 50 ml. conical tube or in tube of viral or Influenza transport media

Storage/Shipping Temperature: Store in refrigerator. Ship cold with cold packs.

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV **Rejection Criteria, specific:** Calcium Alginate swab used; swab with wooden shaft used; specimen not cold on arrival. For Universal rejections, see Section I.

Methodology: Real time Reverse Transcriptase PCR (RT-PCR)

Add. Information: Same swab can be used for Influenza isolation if swab shipped in Influenza or Viral transport media.

CPT Code: Isolation 83890; Amplification 83898; Reverse Transcriptase 83902.

SARS-ASSOCIATED CORONAVIRUS IgG EIA

Synonyms: SARS

Test Section: Virology, 803-896-0819

Days Test Performed: As needed

Request Form: DHEC 1332 Test #122

Special Instructions: Call prior to sending; **DO NOT REMOVE SERUM FROM CLOT**

Specimen & Volume: 5mL whole blood; acute/convalescent; (CONVALESCENT

SPECIMEN MUST BE COLLECTED AT LEAST 29 DAYS AFTER ONSET OF ILLNESS)

Container: red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen; See packing & shipping instruction, Section IV

Rejection: None; for Universal rejections, see Section I

Methodology: EIA

Add. Information: None

CPT Code: 86790

SALMONELLA - See "Enteric Pathogens culture"

SCABIES

Synonyms: Mites, Sarcoptes scabei

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #410

Special Instructions: Place skin scrapings in 1-2 drops of mineral oil on a glass slide and cover

with a cover slip

Specimen & Volume: Skin scrapings from infected area See collection procedure for scabies,

Section III

Container: Cardboard slide mailer in biohazard bag.

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Too much oil used (several drops is too much). For Universal

rejections, see Section I.

Methodology: Microscopic examination Add. Information: Detection of scabies

CPT Code: 87210

SCHISTOSOME ANALYSIS

Synonyms: *Schistosoma haemotobium*, urine for parasites **Test Section:** Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Specimen & Volume:** 15-20 ml Urine **Container:** Clean, dry, screw-capped tube **Request Form:** DHEC 1335, Test #410

Special Instructions: Collect last 15-20 ml of forced morning urine sample **Storage/Shipping Temperature:** Store and ship at Room temperature,

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Stool submitted. For Universal rejections, see Section I.

Methodology: Microscopic examination

Add. Information: Used to detect the presence of Schistosoma haemotobium in urine

CPT Code: 87177

SCHISTOSOMIASIS SEROLOGY - See "Parasite Serology"

SHIGELLA - See "Enteric Pathogens Culture"

SICKLE CELL - See "Hemoglobin Electrophoresis"

SPOROTRICHOSIS SEROLOGY

Synonyms: NA

Test Section: Referred to CDC Mycoses Immunodiagnostic laboratory. 404-639-3469

Days Test Performed: Referred to CDC

Request Form: CDC form Special Instructions: NA

Specimen & Volume: 5 ml Whole clotted blood or 2 ml serum

Container: Red top vacuum tube See Venipuncture procedure, Section III if needed

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: NA **Add. Information:** NA

CPT Code: NA

STAPHYLOCOCCUS- See "Enteric Pathogens Culture" or Aerobe referred for ID

ST. LOUIS EQUINE ENCEPHALITIS - See "Arbovirus Serology"

STREPTOCOCCUS GROUP B - See "Beta-hemolytic Streptococcus, group B culture."

STREPTOCOCCUS PYOGENES (GROUP A) See "Beta-Hemolytic Strep, group A"

SUSCEPTIBILITY TESTING - See "Mycobacterial Susceptibility"

SYPHILIS SEROLOGY SCREEN

Synonyms: RPR, Non-Treponemal Antibody. **Test Section:** Diagnostic Serology, 803-896-0811

Days Test Performed: Monday - Friday

Request Form: DHEC 1332 Test #001 or Test #235,

Special Instructions: NA

Specimen & Volume: 2 ml whole clotted blood or 1 ml serum

Container: Red top vacuum tube See Venipuncture procedure Section III, if needed

Storage/Shipping Temperature: Store and ship at room temperature; Specimen must arrive

within 3 days of collection

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV **Rejection Criteria:** Plasma specimen; more than 24 hours old. For Universal rejections, see

Section I.

Methodology: RPR

Add. Information: Quantitation performed on positives

CPT Code: 86592

T4 LYMPHOCYTES - See "Lymphocyte Subset"

TB CULTURE - See "Mycobacterial Culture"

TETRAHYDROCANNABINOL (THC) (MARIJUANA) See Cocaine & Marijuana

Screen and Drugs of Abuse Screen, Urine

THERAPEUTIC DRUG SCREEN See Anticonvulsant Drug Monitoring

THYROID PANEL

NON-NEONATAL AND CONFIRMATORY NEONATAL

Synonyms: Free T₄ and TSH

Test Section: Clinical labs, Clinical Chemistry unit, 803-896-0891

Days Test Performed: Monday - Friday **Request Form:** DHEC 1332, Test #915

Special Instructions: NA

Specimen & Volume: 1-2 ml serum See Venipuncture procedure, Section III, if needed

Container: Red top vacuum tube

Storage/Shipping Temperature: Store and ship at room temperature.

Shipping Description: Diagnostic specimen. See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: Enzyme Immunoassay Assay (EIA)

Add. Information: NA

CPT Code: TSH-84443, Free T4-84439

TORCH BATTERY

No longer available as battery.

Rubella IgG, test #005 for immune status, test #006 for diagnostic. Toxoplasmosis Serology, CMV IgG and Herpes I and II are not offered.

TOXOCARA - See "Parasite Serology"

TOXOPLASMA SEROLOGY- See "Parasite Serology"

TP-PA SEROLOGY

Synonyms: MHA-TP

Test Section: Diagnostic Serology, 803-896-0811

Days Test Performed: Twice weekly. Usually Monday and Thursday

Request Form: DHEC 1332 Test # 002 and Test # 004

Special Instructions: NA

Specimen & Volume: 0.5 ml serum See Venipuncture procedure, Section III, if needed

Container: Red top Vacutainer

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific None. For Universal rejections, see Section I.

Methodology: Particle Agglutination

Add. Information: Used to determine the stage of infection; Not a screening test

Reactive test is usually reactive for life (85% of cases)

CPT Code: 86781

TREPONEMAL ANTIBODY SEROLOGY See TP-PA

TRICHINOSIS - See "Parasite Serology"

TRICHROME STAIN

Synonyms: Giardia stain, Amoeba (stool exam), Trophozoite stain

Test Section: Bacteriology/Parasitology, 803-896-0804

Days Test Performed: Monday - Friday **Request Form:** DHEC 1335, Test #402

Special Instructions: PVA specimen preferred; Fresh specimen less than 1 hour old accepted **Specimen & Volume:** "Walnut" size formed stool or 2 tbsp liquid specimen mixed well in PVA,

or LV-PVA preservative

Container: Leak-proof screw-cap tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV **Rejection Criteria, specific:** Inadequate mixing of stool and preservative; stool preserved in 10% formalin, SAF, or MIF; fresh stool specimen more than 1 hour old. For Universal rejections, see

Section I.

Methodology: Microscopic examination of stained smears

Use/Add. Information: Used to detect protozoan cysts and trophozoite stages

CPT Code: 88313

TUBERCULOSIS CULTURE - See "Mycobacterial Culture"

TULAREMIA SEROLOGY

Synonyms: NA

Test Section: Referred to CDC Days Test Performed: NA Request Form: CDC Form

Special Instructions: Contact Bacteriology/Parasitology, 803-896-0805

Specimen & Volume: 2 ml Whole blood or serum

Container: Red top vacuum tube See Venipuncture procedure, Section III, if needed

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: NA

Add. Information: Interpretation printed on CDC report

CPT Code: 86000

URINALYSIS:

Test available only in Columbia area when specimen can be delivered directly to the laboratory

Synonyms: NA

Test Section: Clinical Labortories Section, Hematology Unit 803-896-0954

Days Test Performed: Monday-Friday **Request Form:** DHEC 1332, Test # 774

Special Instructions: NA

Specimen& Volume: 10 ml "clean catch" Urine

Container: Plastic urine container

Storage/Shipping Temperature: Not suitable for shipping; Must be delivered to lab

Shipping Description: NA. Do Not ship

Rejection Criteria, specific: Greater than 6 hours old. For Universal rejections, see Section I.

Methodology: Includes microscopic and biochemical examinations

Add. Information: Reference values: sp. Gravity 1.005-1.030, pH 5.0-8.0, other biochemicals

negative, microscopic variable but essentially free of cellular and crystalline elements

CPT Code: 81000

URINE DRUG ANALYSIS- See Drugs of Abuse Screen, urine

URINE LEAD ANALYSIS- See Lead, Urine

VARICELLA VIRUS CULTURE

Synonyms: Chickenpox

Test Section: Virology, 803-896-0819 **Days Test Performed:** Monday - Friday **Request Form:** DHEC 1335, Test #270

Special Instructions: Write Varicella in block on form for Agent/Organism/Virus Suspected

Specimen & Volume: Vesicle fluid

Container: Screw capped tube of viral transport media (Available upon request)

Storage/Shipping Temperature: Store in refrigerator; Ship cold with cold packs; Ship within

24 hours after collection

Shipping Description: Diagnostic specimen. See packing and shipping instructions, Section IV **Rejection Criteria**, specific: Specimen more than 24 hours old when received; Specimen not

cold on arrival. . For Universal rejections, see Section I.

Methodology: Cell culture **Add. Information:** NA

CPT Code: Culture, 87252; Identification, 87253

VARICELLA VIRUS SEROLOGY

Synonyms: NA

Test Section: Virology, 803-896-0819 **Days Test Performed:** Once/Week

Request Form: DHEC 1332, Test #110 for Immune Status

Special Instructions: Please call Virology, 896-0819 prior to sending specimen from a pregnant

patient who has been exposed to varicella

Specimen & Volume: 5 ml. whole blood or 2 ml serum; Single specimen for immune status,

See venipuncture procedure, Section III, if needed

Container: Red top vacuum tube

Storage /Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: None. For Universal rejections, see Section I.

Methodology: EIA

Add. Information: Interpretation: Immune status: Positive, negative or equivocal

CPT Code: 86787

VDRI.

Test only performed on CSF.

Synonyms: NA

Test Section: Virology, 803-896-0819
Days Test Performed: Once a week
Request Form: DHEC 1332, Test #003

Special Instructions: None

Specimen & Volume: 0.5ml -1.0 ml CSF only

VDRL cont.

Container: CSF collection tube

Storage/Shipping Temperature: Store and ship at room temperature

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV Rejection Criteria, specific: Blood submitted. For Universal rejections, see Section I.

Methodology: Slide flocculation

Add. Information: Interpretation: Reactive or non-reactive

CPT Code: 86592

VIBRIO - See Enteric Pathogens Culture

VIRAL CULTURE- See individual viral groups i.e. enterovirus or respiratory virus culture, or individual virus, i.e. Herpes, Influenza CMV, Varicella culture

VIRAL ISOLATE FOR IDENTIFICATION

Synonyms: Referred culture for ID
Test Section: Virology, 803-896-0819
Days Test Performed: Monday-Friday
Request Form: DHEC 1335, Test #275

Special Instructions: None

Specimen & Volume: Tissue Culture Isolate

Container: Screw capped culture tube

Storage/Shipping Temperature: Store and ship at room temperature. Please call prior to shipping so needed culture materials can be obtained. 803-896-0820

Shipping Description: Infectious substance See packing and shipping instructions, Section IV Rejection Criteria, specific: non-viable culture submitted. For Universal rejections, see

Section I.

Methodology: Virus Neutralization, Hemagglutination inhibition

Add. Information: NA

CPT Code: 87253

VIRAL LOAD - See HIV-1 PCR Quantitative (RNA)

VISCERAL LARVA MIGRANS - See "Parasite Serology"

WEST NILE VIRUS SEROLOGY- IgG/IgM

Synonyms: NA

Test Section: Virology, 803-896-0819
Days Test Performed: As needed
Request Form: DHEC 1332, Test # 121

Special Instructions: IgG and IgM on serum specimens. IgM only on CSF.

Specimen & Volume: CSF or 2 ml serum

Container: Sterile vacuum tube or Appropriate tube for CSF collection

Storage/Shipping: **Temperature:** Please call prior to shipping (803-896-0819)

Shipping Description: Diagnostic specimen See packing and shipping instructions, Section IV

Rejection Criteria, specific: Specimen taken too early For Universal rejections see

Section I.

Methodology: EIA

Add. Information: None

CPT Code: 86790

WESTERN EQUINE ENCEPHALITIS - See "Arbovirus Serology"

WHOOPING COUGH - See "Bordetella pertussis"

YERSINIA - See "Enteric Pathogens Culture"

SECTION III

ORDERING SUPPLIES And SPECIMEN COLLECTION

ORDERING SUPPLIES

The Bureau of Laboratories will provide request forms, kits and media and mailing containers for the collection and shipping of laboratory specimens. These supplies are provided free of charge. Please use them judiciously and only to send laboratory specimens to the Department of Health and Environmental Control. Supplies may be obtained by indicating the quantity required on DHEC form 1323, "
Request for Laboratory Supplies". GYN Cytology forms and supplies are ordered on DHEC form 1324 and are available only to DHEC clinics. Call 896-0913 to request these ordering forms or to request supplies.

Collection kits

These kits contain collection materials, request form, an inside screw capped containment container with label, and a cardboard mailing container with a color coded mailing label attached. These are currently accepted by State and private couriers, and the US postal service. Each kit is to be used for only one specimen,

Mycobacteriology (collection kit for TB) Yellow Label Enteric kit (for Bact. Culture) Pink Label Parasitology kit (O & P) Blue Label

Influenza kit (during flu season) Red tube with blue and white envelope

B. pertussis PCR kit

Transport medium (Order request forms and shipping container separately.)

GC Culture medium Viral Transport Media

Regan-Lowe media (for Pertussis)

Mycoplasma hominis/Ureaplasma Order directly from the Virology Section, (803) 896-0819.

Supplies

GC/Chlamydia (for Antigen Detection) Unisex swab or urine collection kit

PPT Tubes for Viral Load

Biohazard Bags

Absorbent Packs

Envelopes (for Newborn Screening and He-HIV blood spots)

Micro tubes for Blood lead---Indicate in blank space on order form

Culturette swabs---Indicate in blank space on order form

Chain of Custody Supplies

Integrity Seals Permanent Marking Pens

Evidence Tape Urine Containers
Diagnostic Specimen labels Temperature strips

Tamper Proof Biohazard Bags

GYN Cytology forms and supplies (for DHEC clinics only) Use DHEC form 1324 to order

Collection Materials

1362 GYN Cytology Request form

Cardboard slide mailer (holds 2 slides)

Shipping Container (for shipping Diagnostic specimens by courier or US postal system)

Mailing containers, screw cap: No. 10 (2 ½" x 6") No. 20 (3" x 6") No. 30 (4" x 6")

Mailing boxes: 4" x 4" 6" x 6" 8" x 8"

Rabies Container

ORDERING SUPPLIES, CON'T.

Shipping Container (for shipping infectious substances)

Hospitals and other clients using a commercial carrier must use special approved mailing containers. These have been distributed, and must be returned for re-use.

Request Forms

The request forms provided by the Bureau of Laboratories are listed below. Forms marked with a + will be pre-addressed with your name, address and sender number. Since an over-supply cannot be returned to stock, please use discretion in the number you request. **DO NOT LOAN OR BORROW** preprinted forms to another client. The preprinted sender number determines where result reports are mailed. Forms are periodically revised. Please discontinue use of old forms once a revision has been made.

A separate DHEC form 1323 must be submitted for each location with a unique sender number.

Form #	Test (revision date)	Form color
1308	+Rabies (02/98)	Lt. Maroon
1310	+Forensic Urine Drug Testing (chain-of custody)	Aqua
1323	Request for Lab Supplies (8/00)	Card stock/buff
1324	Request for GYN Cytology Form and Supplies	Card stock/pink
1327	Newborn Screening (check expiration data on form)	White with green lettering
1332	+Clinical Chemistry	White
1332	Drug Testing	White
1332	+GC/ Chlamydia Screening	White
1332	+Hematology/Urinalysis	White
1332	+ HIV Hepatitis /Syphilis Serology	White
1332	+Immunology	White
1332	+Lead Analysis	White
1332	+Lymphocyte Subset Panel	White
1332	+Prenatal	White
1335	+Bacteriology	White
1335	+Gonococcal Culture	White
1335	+Mycobacteriology	White (Included in kit)
1335	+Parasitology	White (Included in kit)
1335	+Virus Isolation/Herpes	White
1339	+Hemoglobin Electrophoresis (3/95)	Lt. Green
1362	+GYN Cytology 1332(11/01)	Lt. Pink
1812(Temporary)	Newborn Screening Blood Sample Storage Option	White

⁺Preaddressed

DHEC District laboratories forms:

These are available from Central Supply in the Sims/Aycock Building, (803) 898-3498.

INSTRUCTIONS FOR COMPLETING THE TEST REQUEST FORM

Instructions for completing DHEC forms #1332 and 1335 can be found on the back of the forms. The instructions below are for all other forms.

Please note the highlighted areas on the forms you receive. These are the data elements that will appear on your result report. Information entered in other areas on the request form will not be returned to you on the result report. PLEASE TYPE OR PRINT ALL ENTRIES AND PROVIDE ALL INFORMATION REQUESTED.

<u>Date Received and Laboratory Specimen Block</u> (upper right corner) **for our Laboratory's use only**.

- 1. Patient Name: Enter last name, first name and middle initial,
- 2. Patient Birth date: Enter month, day, year. Example: Sept. 1, 1983 is written 09-01-1983.
- 3. Race: Insert appropriate initial as outlined below: (DO NOT USE NUMBERS)

A = Asian B=Black/African American

W = White I = American Indian/Alaskan Native

P = Native Hawaiian/Other Pacific Islander O = Other

U = Unknown/Unclassified

- 4. Sex: Mark "X" (if blocks are indicated) Or enter M (Male), F (Female), T (transsexual)
- 5. <u>Social Security #</u> Enter patient's social security number
- 6. MCI ID: (Used by DHEC clinics.) Enter patient's MCI number
- 8. <u>Other I.D./Physicians:</u> To further identify or route the report. Numbers or letters may be used. Example: Patient medical record number
- 9. <u>Diagnostic Code:</u> Enter ICD-9 code (only required for Cytology)
- 10. <u>County of Residence:</u> Write the code number for the county in which the patient lives (see Table 1)
- 11. <u>Sender's Name and Mailing Address:</u> If not pre-addressed, enter a complete postal mailing address.
- 12. <u>Sender Number:</u> This number is used in the computer system to determine where the results will be sent. Most forms will be pre-addressed with the sender name, address and number. See Table 2 for Sender numbers.
- 13. <u>Billing Number:</u> This number is necessary only if the test is to be billed to someone other than the sender. It is assigned by the Bureau of Laboratories. Call 896-0810 to obtain a number
- 14. <u>Program Number:</u> This space is to be completed only on specimens being submitted by County Health Departments. See Table 3 for the appropriate code numbers.
- 15. Medicaid Number: If test can be billed to Medicaid, complete this space.
- 16. <u>Specimen Information:</u> Mark appropriate boxes. <u>Date and time collected are now required by CLIA</u>. (This sometimes appears in another location on the form.)
- 17. Other Information: This section is for other information pertinent to the test(s) requested. Please complete as indicated.
- 18. <u>Test Request:</u> Mark test requested. This item determines the test(s) that will be performed.
- 19. <u>Sender Copy:</u> Tear off back copy of the request form and file for future reference as necessary.
- 20. Provider Code: (Cytology only) Enter Provider Code.

TABLE 1 COUNTY CODES

Abbeville	01	Greenwood	24
Aiken	02	Hampton	25
Allendale	03	Horry	26
Anderson	04	Jasper	27
Bamberg	05	Kershaw	28
Barnwell	06	Lancaster	29
Beaufort	07	Laurens	30
Berkeley	08	Lee	31
Calhoun	09	Lexington	32
Charleston	10	Marion	33
Cherokee	11	Marlboro	34
Chester	12	McCormick	35
Chesterfield	13	Newberry	36
Clarendon	14	Oconee	37
Colleton	15	Orangeburg	38
Darlington	16	Pickens	39
Dillon	17	Richland	40
Dorchester	18	Saluda	41
Edgefield	19	Spartanburg	42
Fairfield	20	Sumter	43
Florence	21	Union	44
Georgetown	22	Williamsburg	45
Greenville	23	York	46

TABLE 2 SENDER NUMBERS

Private Physician Use your S.C. Medical License number preceded by the letter M.

Group Practice

A number preceded by the letter G will be assigned to group practices at their request. Use of the group number will insure that a single bill will be sent for tests submitted by all physicians in the practice. If you desire to be billed in this manner, please contact (803) 896-0810 for assignment of a group number. If each physician wishes to be billed separately, use the appropriate Medical License number.

Hospital

Use the hospital license number preceded by the letter H. If the test result is to be mailed directly to the patient's physician, use the physician's name, address and sender number in the appropriate spaces on the form and write the **hospital license number preceded by H in the billing number space.**

Private Laboratory

A number assigned by the Bureau of Laboratories. If not known, contact the Bureau at (803) 896-0810 for assignment.

DHEC County

Health Depts. The assigned county code number preceded by a C.

BILLING NUMBERS

A billing number is only necessary if the test is to be billed to someone other than the sender. It is assigned by the Bureau of Laboratories. Call (803) 896-0810 to obtain a number.

TABLE 3 PROGRAM NUMBERS

	I KOGRAM NUMBERS	
Used only when billing to a DHEC Program		
0001	Maternal and Child Health	
0002	Children Rehabilitative Services	
0003	Children Health	
0004	Family Planning	
0005	Sickle Cell Program	
0007	Cancer Control	
8000	Heart Disease Control	
0009	Tuberculosis Control	
0010	Chronic Disease Detection	
0011	STD Control	
0012	Home Health Services	
0017	Migrant Health	
0025	District/Health Dept. Program	
0027	Metabolic Screening Program	
0035	STD Enhanced Project	
0043	Environmental Sanitation	
0050	Early and Periodic Screen, Diagnosis and Treatment	
0053	Edisto HIV/AIDS Consortia	
0054	Medicaid Eligible	
0063	Employee Health Services	
0070	Communicable Disease Control	
0072	HIV-AIDS Alcohol & Drug Abuse Referrals	
0089	Health Hazard Evaluation	
0095	WIC	
0099	Indigent (Not Eligible For Medicaid)	
0101	High Risk Maternity	
0110	STD-Chlamydia Study	
0111	AIDS Bureau of Preventive Health Services	
0202	Immunization Program	
0203	Hepatitis B - Infants & Children Contacts	
0204	ICSC Syphilis Project	
0299	Syphilis Elimination	
0242	Family Dlamina HIV Count	

0343 Family Planning HIV Grant

SPECIMEN COLLECTION PROCEDURES VENIPUNCTURE PROCEDURE

Precaution:

Wear Gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

Collection Procedure:

- 1. While putting on the appropriate PPE, explain the procedure to the patient.
- 2. Position the patient for taking blood.
- 3. Apply tourniquet to the arm just above the elbow and instruct patient to make a fist.
- 4. Select the best vein and cleanse the skin over the site with 70% alcohol; allow to dry.
- 5. Use sterile needle screwed on holder. Vacuum collection tube may be inserted into holder without danger of breaking the vacuum.
- 6. Insert the needle into the vein and collect required tubes of blood. Orders for multiple tests may require more than 1 tube of clotted blood.
 - Note: Collect blood in plain (red stopper) tubes before collecting blood in tubes with additives (e.g. EDTA) Mix tubes with additives well to prevent clotting.
- 7. Release tourniquet, withdraw needle from vein and apply pressure on venipuncture site with dry sponge (cotton). Do not cover the injection site with an alcohol sponge while withdrawing needle.
- 8. Have patient apply pressure on the venipuncture site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site no longer bleeds, a bandage may be applied if desired.
- 9. Label specimen tube with proper patient identification information.
- 10. Complete all requested information on the test request form.
- 11. Properly dispose of needles (in biohazard puncture proof sharps container) and other contaminated materials used during venipuncture.

Serum Specimen Preparation:

- 1. Allow the tube of blood to remain undisturbed in an upright position at room temperature for 20-30 minutes.
- 2. After clot has formed gently loosen clot at the top; "rim" with a sterile applicator stick if necessary.
- 3. Centrifuge tubes for 10-15 minutes.
- 4. Remove serum carefully with sterile transfer pipet and transfer to a clean sterile rubber-stoppered tube or to a screw-top vial. Avoid transferring any red cells.
- 5. Label tube or vial with patient's name and/or code number running up the tube. Do not wrap around or Flag the label by pressing ends together and extending from the tube.
- 6. Store tubes of labeled serum in refrigerator (2°-8° C) until ready to ship to the laboratory.

If using separator (gel) tubes omit steps 2 and 4 above. Be sure gel forms a distinct barrier between serum and clot.

If sending whole blood in vacutainer tube, omit steps 2-4. Store at room temperature.

See individual tests in Section II for specific instructions.

DRIED BLOOD SPOTS FOR NEWBORN SCREENING HEEL-STICK PROCEDURE

Supplies:

The filter paper to be used in the collection of the specimen for the initial testing is attached to DHEC form 1327. This form is not pre-addressed because of the filter paper. However, pre-addressed envelopes for mailing are available See page III-1 to order.

Preparation:

Blood should be collected **at least 24 hours after birth** or as closely as possible to the time of discharge from the hospital. If discharged early, specimens collected from infants receiving only non-lactose containing feedings must be clearly marked as such.

Cord blood is NOT acceptable for newborn screening in SC and should never be applied on the filter paper collection form.

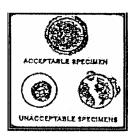
To aid in getting sufficient circulation to collect an adequate sample,

You may place the infant's foot in warm water (no higher than 104°F) for 3 minutes, or wrap in a warm moist towel or diaper.

Collection Procedure:

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

- 1. Cleanse infants heel with 70% isopropyl alcohol (use only rubbing alcohol)
- 2. Allow heel to air dry
- 3. The puncture should be within the area shown.
- 4. Using lancet, perform puncture while holding the infants limb in a dependent position
- 5. Gently wipe off first drop of blood with sterile gauze or cotton ball (initial drop contains tissue fluid).
- 6. Wait for spontaneous flow of blood
- 7. Apply gentle pressure with thumb & ease intermittently as drops of blood form
- 8. Touch printed side of filter paper to the blood spot & fill each printed circle with a SINGLE application of blood. The filter paper should touch only the drop of blood and should not be pressed against the skin around the puncture. Observe the saturation of each printed circle as the blood flows through the filter paper. Spotting should be done only on the printed side. Do not layer successive drops of blood on the circle. If blood flow diminishes, repeat steps 1-8 to completely fill the circles When properly filled, the blood spot will be the same size on both sides of the filter paper.
- 9. Allow blood specimen to AIR dry thoroughly on level non absorbent surface such as a plastic coated test tube rack at least 4 hours at room temp. DO NOT stack or heat to dry.
- 10. Place dried filter paper forms into mailing envelope provided **Mail within 24 hours** by first class mail



Heel-stick procedure, cont.

Special Circumstances:

Transfusion:

If the infant is to undergo a transfusion of blood products, a specimen should be obtained prior to the transfusion. If this is not possible, collect the specimen and mark the form "Transfused Yes" indicating the date of the most recent or last transfusion. Infants who receive transfusions should have a repeat hemoglobinopathy screening 2 months after the date of the last transfusion.

Do not mark the "Transfused yes" box if the transfusion took place 2 months before the collection date.

Premature Infants

In premature infants, the results can be falsely abnormal.

If the infant is on a lactose containing feeding, the specimen should be collected at least 24 hours after birth.

If the infant is receiving only IV fluids or total parenteral nutrition, the specimen may be collected at least 24 hours after birth and the lab slip marked "TPN" or "NPO"

All premature infants should receive their initial screening by 7 days of age regardless of their health status.

PITFALLS

- 1. Failure to wipe off alcohol residue may dilute the specimen and adversely affect test results.
- 2. Puncturing the heel on posterior curvature will permit blood to flow away from puncture, making proper spotting difficult. DO NOT LANCE ON PREVIOUS PUNCTURE.
- 3. Milking or squeezing the puncture may cause hemolysis and a mixture of tissue fluids with the blood.
- 4. Capillary tubes may be used; however, we do not recommend this procedure since application of blood with a capillary tube results in scratching the surface of filter paper, adversely affecting test results.
- 5. Avoid touching area within filter paper circles before blood is applied.
- 6. Do not allow water, feeding formulas, antiseptic solutions, etc. to come in contact with the sample.
- 7. Do not place filter paper in the envelope until thoroughly dry.
- 8. Insufficient drying adversely affects test results.
- 9. DO NOT mash blood into filter paper.
- 10. DO NOT staple or tape flap over blood spots.
 - DO NOT SHIP DRIED BLOOD SPOT SPECIMENS IN PLASTIC BAGS.

DRIED BLOOD SPOTS FOR HIV TESTING FINGERSTICK PROCEDURE

Supplies:

If a serum specimen cannot be obtained for HIV testing, dried blood spots from capillary blood may be substituted. The filter paper to be used in the collection of dried blood spots for HIV testing is attached to DHEC form 1339, the HEMOGLOBIN ELECTROPHORESIS/HIV REQUEST FORM. The block, 230 BLOOD SPOT HIV-1, in the lower right-hand corner must be checked. Envelopes for mailing specimen are also available. See Page III-1 to order

Note: For infants less than one year puncturing the heel is recommended See heel-stick procedure, page III-8 For older patients finger stick capillary blood is satisfactory

Capillary Blood Collection Procedure:

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.:

- 1. Cleanse the 3rd or 4th finger with alcohol and dry with sterile gauze.
- 2. Puncture finger with sterile, disposable lancet.
- 3. Wipe away first drop of blood.
- 4. When next large drop of blood appears, touch filter paper circle to blood. Do not touch the filter paper to the skin around the puncture.
- Make single applications filling each circle. Do not superimpose blood drops.
 Be sure that the filter paper is saturated with blood through to the other side.
 When properly filled, the blood spot will be the same size on both sides of the filter paper.
 Do not send the specimen if the circles are not completely filled. Collect a second sample.
- 6. Allow the specimen to dry at room temperature **for at least 4 hours** or overnight.
- 7. Place dried filter paper specimen into mailing envelope provided
 - Do not ship dried blood spot specimens in plastic bag.
- 8. Mail to laboratory within 24 hours by first class mail.

 Note: All the circles are needed if tests have to be repeated or additional tests run.

PITFALLS

- 1. Failure to wipe off alcohol residue may dilute the specimen and adversely affect test results
- 2. Milking or squeezing the puncture may cause hemolysis and a mixture of tissue fluids with specimen.
- 3. Use of a capillary tube is not recommended since application of blood with a capillary tube results in scratching the surface of filter paper, adversely affecting test results.
- 5. Avoid touching area within filter paper circles before blood is applied.
- 6. Do not place filter paper in the envelope until thoroughly dry.
 Insufficient drying adversely affects test results. Allow at least 4 hours drying time and **DO NOT ship in plastic bags.**

SPECIAL COLLECTION PROCEDURES FOR BLOOD LEAD

Finger/heel-sticks are appropriate for screening. They require vigorous cleaning and attention to detail to prevent contamination of the sample during collection. Venipuncture is used for confirmation of an elevated finger/heel-stick. All three collection methods provide a quantitative result. EDTA microtainers are available for finger and heel sticks. Use DHEC form 1332.

Preparation:

Routine procedures for the collection and handling of potential infectious materials should be observed. The collector should wash his hands and glove with dust-free gloves before preparing the patient for specimen collection. Gloves which have dust on the exterior surface should be rinsed off with tap water.

Venipuncture:

- 1. Scrub the collection site with an alcohol wipe.
- 2. Dry with gauze.
- 3. Repeat steps 1 and 2.
- 4. Do venipuncture. Use 3 ml or larger vacuum tube containing EDTA anticoagulant.
- 5. Mix the blood immediately after collection with the anticoagulant by gently rocking the specimen end to end several times.
- 6. Label tube with patient's name running up the tube. If using a paper label, do not wrap label completely around tube. Press loose ends together to form a flag.
- 7. Complete DHEC form 1332. See instructions on back for completing.

Fingerstick:

NOTE: Puncturing the fingers of infants less than 1 year of age is not recommended.

Puncturing the heel is more suitable for these children (NCCLS, 1999).

- 1. Cleanse child's 3rd or 4th finger with an alcohol wipe.
- 2. Blot dry with gauze.
- 3. Repeat steps 1 and 2.
- 4. Puncture finger with sterile lancet.
- 5. Allow the first drip of blood to fall onto gauze.
- 6. Touch the lip of collection tube into the blood and fill ¾ full.

 Gently massage finger to keep blood flowing. Tilt the tube slightly
- 7. After sample has been collected, instruct mother to hold gauze on the child's finger until bleeding stops.
- 8. IMPORTANT: Immediately after collection, mix blood thoroughly with the anticoagulant in the tube by gently rocking the tube end to end 8 times.
- 9. Label tube with patient's name and date of collection. Wrap label around tube and press loose ends together to form a flag extending from the tube. Do not wrap label around cap
- 10. Complete DHEC form. 1332

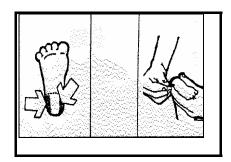
See instructions on back for completing

Heel-stick (Used for children less than 1 year of age)

- 1. Cleanse infant's heel with an alcohol wipe.
- 2. Blot dry with gauze.
- 3. Repeat steps 1 and 2.
- 4. Using lancet perform puncture as illustrated. Stay within the shaded areas.

Blood Lead Collection procedures, cont

- 5. Allow first drop of blood to fall onto gauze.
- 6. Touch the lip of collection tube into the blood and fill ¾ full. Gently massage the heel to keep blood flowing. Tilt tube slightly outward from heel. Gradually lower the tube as it fills. Apply gentle pressure with thumb and ease intermittently to maintain blood flow.



- 7. After sample has been collected, instruct the mother to hold gauze on the child's heel until bleeding stops.
- 8. IMPORTANT: Immediately after collection, mix blood thoroughly with the anticoagulant in the tube by gently rocking the tube end to end 8 times.
- 9. Label tube with patient's name and date of collection. Wrap label around tube and press loose ends together to form a flag extending from the tube.
- 10. Complete DHEC form 1332. See instructions on back for completing.

Specimen Preservation and Transport

Refrigeration is not required, but is recommended prior to shipment. It is not necessary to refrigerate the specimen during shipment. Mail specimens to the laboratory the same day they are collected if possible. See section IV for appropriate shipping container, packaging and transport instructions.

SPECIMEN COLLECTION PROCEDURES HEPATITIS C (HCV) TOTAL ANTIBODY and QUANTITATION (RNA)

Note: This test is only available for DHEC HCV project sites or by special request

Principle:

To properly collect a blood specimen for Hepatitis C, total antibody testing by EIA, and /or PCR Quantitation (RNA) and confirmation by RIBA

Patient preparation:

No special preparation

Supplies:

- 1. 1 Serum separator tube
- 2. Cold packs for shipping
- 3. DHEC form1332

Collection Procedure:

Precaution: Wear gloves when collection blood samples

- 1. Use serum separator tube, and Collect a full tube of blood
- 2. Allow to clot at room temperature and centrifuge within four hours of collection.

 Invert the tube after centrifugation to verify that the serum separator is intact and no cells enter the serum. If cells enter the serum, repeat centrifugation. Same specimen can be used for both tests

Specimen Handling:

- 1. Write the patient's name on the serum separator tube or use a patient label.
- 2 Complete a DHEC form 1332 .See instructions on back of form for completing Mark test # 224.

Specimen Preservation and Transport

- 1. Place the sample in a container with enough cold packs to maintain a temperature of 2° to 8° C during shipment. Sample must arrive at the laboratory within 24 hours of collection.
- 2. Label the outside of the container as HCV Viral Load

 Note: The HCV samples can be shipped with HIV-I RNA Viral Load samples if desired.
- 3. See section IV for appropriate shipping container, packaging and transport instructions.

Causes for Specimen Rejection:

- 1. Serum separator tube not used
- 2. Specimen not shipped with cold packs or specimen not cold on arrival.
- 3. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF ENTERIC PATHOGENS

Principle:

To properly collect a stool specimen for the isolation of the following enteric pathogens: *E coli 0157*, Salmonella, Shigella, Yersinia, Campylobacter, Vibrio, Staphylococcus, Clostridium perfringens and Bacillus cereus.

Patient Preparation:

No special preparation.

Supplies:

- 1. Wide-mouthed container.
- 2. Enteric kit with Cary-Blair transport media. See page III-1 to order.
- 3. DHEC form 1335

Collection Precautions:

Wear gloves when collecting stool specimens.

Collection Procedure (Stool):

- 1. Collect stool in a clean (not necessarily sterile) wide-mouthed container with a tight-fitting lid. These containers must be free of preservatives and detergents.
- 2. Do not collect specimen from toilet. Avoid contamination with urine.
- 3. Infant specimens may be collected in a disposable diaper with plastic side facing inside.
- 4. Collect a walnut sized piece if stool is formed or 5-10 ml if stool is liquid.

Cary-Blair Transport media

Formed feces: use tongue depressor or spoon inside the lid to transfer walnut size portion of stool. Liquid feces: use pipette to transfer 5-10 ml of liquid stool to the transport media. Replace cap on tube and refrigerate until transported.

Specimen Handling:

- 1. Place a patient identification label on the transport medium
- 2. Complete a DHEC form 1335 to accompany specimen. See instructions on back of form Be sure to complete additional test specific information

Specimen Type/Source: Mark X by Feces

Date Collected

Organism Suspected: Indicate name of suspected organism

NOTE: Routine culture includes testing for *Salmonella*, *Shigella*, *Campylobacter*, *and E. coli 0157*. Request for other specific pathogens must be indicated on the laboratory request form.

Test Requested: Mark 508 Enteric Culture.

Specimen Preservation and Transport:

- 1. Ship specimens in transport media in cooler with cold packs. Specimen should be received within 48 hours of collection.
- 2. See section IV for appropriate shipping container, packaging and transport instructions

- 1. Specimen too old.
- 2. Use of improper transport media or transport conditions.
- 3. Insufficient quantity
- 4. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF NEISSERIA GONORRHOEAE

Principle:

To properly collect an eye culture, rectal culture and oropharyngeal culture for the diagnosis of *Neisseria gonorrhoeae*. To properly collect a cervical, urethral and vaginal culture in cases of assault or sexual abuse

Patient Preparation:

For male urethral culture: The patient should not have voided for at least 1 hour before performing a culture, especially men without a discharge.

Supplies:

- 1. Sterile Dacron or Rayon swab
- 2. Sterile thin, flexible wire with Dacron or Rayon swab (males)
- 3. GC culture kit with Transgrow bottle for *N. gonorrhoeae* .See page III-1 to order.
- 4. DHEC form 1335
- 5. Speculum (cervical, vaginal)

Collection Precautions: (All specimens)

Wear Disposable Gloves And Protective Eye Wear When Collecting And Handling Specimens.

Collection Procedure: (Eye)

- 1. Touch a sterile swab to purulent discharge. If necessary, lower eyelid may be pulled down and the swab touched to the conjunctival mucosa.
- 2. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium

Collection Procedure: (Rectal)

- 1. Have the patient bear down slightly for ease in insertion of swab.
- 2. Insert a sterile swab approximately 3 cm into the anal canal using lateral pressure to avoid entering any fecal mass. If gross fecal contamination of the swab occurs, it should be discarded into a biohazard container and a repeat specimen obtained.
- 3. Rotate the swab to sample crypts just inside the anal ring and allow the swab to remain in the anal area for several seconds for better absorption onto the swab.
- 4. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium.

Collection Procedure: (Oropharyngeal [Throat])

- 1. Using a tongue blade to hold the tongue down, take a specimen directly from the back of the throat, carefully avoiding contact with teeth, cheeks, gums or tongue when inserting or removing the swab.
- 2. Rub a sterile swab over the back wall of the throat and tonsillar crypts.
- 3. Inoculate Transgrow bottles as described under Inoculation of Transgrow Medium.

Collection Procedure: (Cervical)

- 1. Obtain the cervical specimen with the aid of a speculum that has been moistened with water. Other lubricants may contain antibacterial agents.
- 2. Insert the speculum and if unable to visualize the cervical os, remove excess mucus with swab.
- 3. Insert another sterile swab into the endocervical canal approximately 2-3 cm. Move the swab in a rotary motion for a few seconds to permit absorption of the exudate. If the patient is pregnant, and there has been no vaginal bleeding, insert swab into the endocervix only until the tip is no longer visible and rotate gently for a few seconds).
- 4. Inoculate Transgrow bottles as described under inoculation of Transgrow medium.

Collection Procedure: (Vaginal) for Children and Hysterectomy Patients Only

- 1. Insert the speculum.
- 2. With a sterile swab obtain the specimen from the posterior vaginal vault.
- 3. Allow a few seconds for absorption of material.
- 4. If the hymen is intact, a swab of the vaginal orifice will suffice.
- 5. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium.

Collection Procedure: (Urethral Culture - Females)

- 1. Massage the urethra against the pubic symphysis from vagina to orifice to express discharge.
- 2. If no discharge is evident, insert a sterile flexible thin wire swab approximately 2 cm into the urethra and rotate for several seconds.
- 3. Withdraw swab and inoculate Transgrow bottle as described under Inoculation of Transgrow

Collection Procedure: (Urethral - Males)

- 1. Insert a sterile flexible swab with a thin wire shaft 2-4 cm into the urethra.
- 2. Once inserted, rotate the swab gently to ensure contact with all urethral surfaces.
- 3. Leave inserted for 2-3 seconds for better absorption of material.
- 4. Withdraw swab and inoculate Transgrow bottle as described under Inoculation of Transgrow.

Inoculation of Transgrow Medium

- 1. Have Transgrow at **room temperature**; **check the expiration date** before inoculation.
- 2. Hold the bottle in an upright position. Remove the cap only when ready to inoculate.
- 3. Soak up excess moisture in the bottle with the specimen swab and roll the swab from side to side over the entire surface of the medium starting at the bottom of the bottle.
- 4. Remove swab from bottle and discard into a biohazard container.
- 5. Recap the bottle tightly.

Specimen Handling:

- 1. Place label with patient's name on back of Transgrow bottle where chocolate colored medium is layered. **Do not place label on clear side of bottle**. This window is needed to observe growth.
- 2. Complete a DHEC form 1335 to accompany specimen. See instructions on back of form Be sure to complete test specific information.

Specimen: Mark X by the appropriate type and write in the site.

Was Culture Incubated Before Transport?: mark X in the appropriate space(s).

<u>Test Requested:</u> Mark X in the appropriate space.

Specimen Preservation and Transport:

- 1. Place the Transgrow bottle in an upright position in an incubator set at 35°C as soon as possible after inoculation. **Never refrigerate the medium after inoculation as cold temperature will rapidly kill gonococci.** Incubate until ready to ship,
- 2. If an incubator is not available, make sure culture is shipped on the same day as collected.
- 3. If the specimen is collected on Friday and cannot be shipped until Monday, incubate over the weekend, but remove first thing Monday morning to prevent contaminant overgrowth.
- 4. If state courier is used, cultures collected on Friday may be shipped on Friday and marked as not incubated.
- 5. See section IV for appropriate shipping container, packaging and transport instructions.

- 1. Transgrow media not used or Transgrow media expired.
- 2. Specimen in transit for more than 5 days.
- 3. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF GROUP A BETA HEMOLYTIC STREPTOCOCCUS OR DIPHTHERIA

Principle:

To properly collect a throat swab for the culture of Beta Strep Group A or C. diphtheria

Patient Preparation:

No special preparation.

Supplies:

- 1. Culturette swab kit containing Stuart's medium Use form 1323 to order and indicate culturette in blank space on form
- 2. DHEC form 1335

Collection Procedure for Throat Swab:

- 1. Shine a bright light if possible over the shoulder of the specimen collector into the oral cavity of the patient so that the swab can be guided to the posterior pharynx.
- 2. The patient is instructed to tilt his/her head back and breathe deeply.
- 3. Depress the tongue with a tongue depressor to help visualize the posterior pharynx. Use culturette kit. Do not use calcium alginate swabs.
- 4. Extend the swab to the back of the throat between the tonsillar pillars and behind the uvula.
- 5. Have the patient phonate a long ash which will lift the uvula and help to prevent gagging.
- 6. The tonsillar areas and posterior pharynx should be firmly rubbed with the swab.
- 7. Care should be taken not to touch the teeth, cheeks, gums or tongue when inserting or removing the swab to minimize contamination with normal mouth flora.
- 8. After collection, place the swab back into the culturette and break or squeeze the ampule. Note: Notify the DHEC Bacteriology Section (803-896-0805) when a diphtheria specimen is to be collected so that special isolation media can be prepared.

Specimen Handling

- 1. Place a patient label on a culturette swab kit.
- 2. Complete a DHEC form 1335 to accompany specimen. See instructions on back of form Be sure to complete test specific information:

Specimen Site: Mark X in the appropriate space and enter the site.

<u>Test Requested</u>: Mark X in the appropriate space.

Organism suspected: Indicate Group A strep or diphtheria

Specimen Preservation and Transport

- 1. Store and ship culturette at room temperature
- 2. See section IV for appropriate shipping container, packaging and transport instructions

- 1. Ampule in culturette not crushed.
- 2. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF GROUP B BETA-HEMOLYTIC STREPTOCOCCUS

Principle:

To properly collect a vaginal or rectal culture for the detection of beta-hemolytic Group B Streptococcus or *Streptococcus agalactiae*.

Patient Preparation:

No special preparation.

Supplies:

- 1. Culturette swab kit Use form 1323 to order and indicate culturette in blank space.
- 2. DHEC form 1335
- 3. Speculum

Collection Procedure: (Vaginal)

- 1. Insert the speculum.
- 2. With the Culturette swab obtain the specimen from the posterior vaginal vault.
- 3. Allow a few seconds for absorption of material.
- 4. Place the swab back into the culturette and break or the ampule.

Collection Procedure: (Rectal)

- 1. Have the patient bear down slightly for ease in insertion of swab.
- 2. Insert the culturette swab approximately 3 cm into the anal canal using lateral pressure to avoid entering any fecal mass. If gross fecal contamination of the swab occurs, discard into a biohazard container and another specimen obtained.
- 3. Rotate the swab to sample crypts just inside the anal ring and allow the swab to remain in the anal area for several seconds for better absorption of organisms.
- 4. Place the swab back into the culturette and break the ampule

Specimen Handling:

- 1. Place a patient label on the culturette swab kit.
- 2. Complete a DHEC form 1335 to accompany specimen **See instructions on back of form** Be sure to complete additional test specific information

Specimen Site

Organism Suspected:

Test Required: Mark Test #510 Non-Enteric Culture & ID

Specimen Preservation and Transport:

- 1. Store and ship culturette at room temperature
- 2. Specimen should reach laboratory within 48 hours of collection
- 3. See section IV for appropriate shipping container, packaging and transport instructions.

- 1. Ampule in culturette not crushed.
- 2. Swab contaminated with feces
- 3. Specimen in transit more than 2 days
- 4. Universal rejections, Section I

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SPECIMEN COLLECTION FOR CULTURE OF MYCOBACTERIUM (TB)

Principle:

To properly collect a sputum or urine specimen for the diagnosing and monitoring of tuberculosis and other mycobacterial infections.

Supplies:

- 1. (a) Mycobacteriology collection kit (50 ml plastic sputum collection tube, metal can and cardboard mailing container) See page III-1 to order.
 - (b) Sterile screw cap container with a round opening of at least 2 inches for urine
- 2. DHEC form 1335
- 3. Particulate respirator (PR)

Collection Procedure: (All Specimens)

Wear Disposable Gloves and a Particulate Respirator When Collecting Specimens

Patient Preparation: (Sputum)

- 1. Explain to patient the importance of how to collect and handle a sputum specimen. Give the patient the sputum collection kit and COLLECTION OF SPUTUM SPECIMENS FOR MYCOBACTERIA (TB) sheet.
- 2. If the nurse must remain with the patient while he/she is coughing, the nurse should wear a particulate respirator.
- 3. Have the patient collect an early morning sputum sample.
- 4. Ask the patient to breathe deeply, exhale, and then cough deeply. Steam from a hot shower or a boiling kettle may help to stimulate the flow of secretions. Also, drinking several cups non alcoholic liquids will assist in raising sputum.
- 5. Patient should brush his/her teeth and/or rinse with water, not an antiseptic solution before obtaining the sputum specimen to reduce the overgrowth of mouth flora,
- 6. The patient should submit a series of three (3) sputum samples over a period of three days (one/day), if specimens are being collected for initial diagnosis.

Collection Procedure (Sputum)

- 1. Remove the cap from the sterile container without touching the inside of the container. This will avoid contamination of the specimen which results in having to submit another specimen.
- 2. Patient is instructed to take a deep breath, hold it momentarily and cough deeply from the deepest part of the chest. Saliva and nasal secretions which contain few acid-fast bacteria are not to be collected.
- 3. Instruct the patient to spit the sputum into the appropriate sterile container until at least 5 ml or 1 teaspoon is obtained. Replace cap on the container. A minimum of 5 ml is needed for culture.
- 4. Avoid soiling the outside of the container. If soiling does occur, wipe with a clean cloth wet with alcohol soap and water, or 1:10 bleach solution, and then wash hands.
- 5. Sputum specimens should be free of food particles and other extraneous material.
- 6. Place the cap on plastic tube or sterile container and screw to close tightly.

If patient is to collect sputum in the home, give patient sputum collection and mailing containers and instruction sheet on how to obtain a sputum sample.

Collection Procedure: (Urine)

The patient should submit a series of three (3) urine samples over a period of three days (one/day) if specimens are being collected for initial diagnosis.

Female- midstream voided:

- 1. Have patient thoroughly clean the urethral area with soap and water.
- 2. Instruct patient to sit on toilet, and to manually separate labia minora with one hand and keep them separated while voiding the first portion of urine into the toilet.
- 3. After several ml have passed, have patient collect the midstream portion into the specimen container without stopping the flow of urine. Try to avoid touching the lip or inside of the container with the hand.
- 4. Have the patient finish voiding into the toilet.
- 5. Amount of urine needed is 10 ml. Screw cap on plastic tube to close tightly.

Male-midstream voided:

- 1. Clean the glans with soap and water.
- 2. While holding foreskin retracted, begin voiding.
- 3. After several ml have passed collect the midstream portion into the appropriate container without stopping flow of urine.
- 4. Have the patient finish voiding into the toilet.
- 5. Amount of urine needed is 10 ml. Screw cap on plastic tube to close tightly.

For collection procedures on other specimens see chart on Collection and Shipment of Mycobacterial Specimens.

Specimen Handling:

- 1. Place a patient identification label on the 50 ml screw capped tube.
- 2. Complete a DHEC form 1335 to accompany specimen See instructions on back of form Be sure to complete test specific information:

Agent suspected: Enter the suspected agent

Specimen source: Mark "X" by the appropriate source.

Date & Time Collected:

NOTE: <u>All clinical specimens</u> should be ordered using Test Code 601. Test Code 602 is reserved exclusively for laboratories that have isolated Mycobacteria and need them identified. Do not request drug susceptibility testing (Test Code 604) when submitting specimens from suspected new cases of tuberculosis. <u>All</u> initial isolates of M. tuberculosis will be tested for susceptibility to INH, rifampin, ethambutol, streptomycin and pyrazinamide.

Specimen Preservation and Transport: Sputum:

- 1. Refrigerate samples if shipping is delayed over 24 hours. This will decrease overgrowth of other microorganisms which delay culture results.
- 2. Place the collection tube in the metal can and close screw cap securely. Be sure neither plastic tube nor metal can are soiled with sputum or urine.
- 3. Wrap the completed DHEC 1335 laboratory form around the metal can. Be sure the date the specimen was collected is on the form. If the laboratory form is around the plastic tube instead of the metal can the laboratory must autoclave it before it can be handled.
- 4. Place the metal can in the pre-addressed, round cardboard mailing container
- 5. Mail specimen on the day it was collected, if possible, but do not mail specimen on Fridays. Refrigerate the carton until mailed.

Specimen Preservation and Transport Urine.

- 1. If specimen is urine, ship cold with cold packs.

 Place a plastic bag over the fiberboard carton and place in a Styrofoam cooler with cold packs for transportation.
- 2. Label outside of cooler as Urine for TB testing

Specimen Rejection:

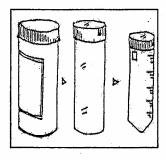
- 1. Specimen broken or leaked in transit. Sterile body fluids may be processed with the approval of the Supervisor or Division Director.
- 2. Specimen > 5 days old.
- 3. Universal rejections, see Section I

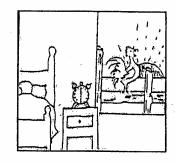
SPECIMEN COLLECTION FOR CULTURE OF MYCOBACTERIA (TB)

SPECIMEN TYPE	TIME	AMOUNT	NUMBER	SPECIAL PROCEDURE
Sputum	Early AM On Waking	5-10 ml.	Series of 3 One/Day	Sputum-material coughed up from deep in lungs-not saliva
Urine	Early AM	Entire specimen, centrifuge 10 ml.	Series of 3 One/Day	Voided midstream specimen collected as aseptically as possible. Transport to lab immediately.
Gastric Washing	Early AM	10 ml.	1 or more as needed	No food after midnight. Pass 20-50 ml. sterile distilled water through stomach tube and draw off specimen in sterile tube.
Biopsy				
Feces		Formed-send walnut sized portion Liquid-send 10 ml.	1 or more as needed	No fixative or preservatives (saline only)
Sterile body fluids other than blood		10 ml.	1 or more as needed	
Swabs of drainage or other material				Use small amt of sterile saline to keep swab moist. Do not use transport media. Swabs are not usually productive specimens for mycobacteria.

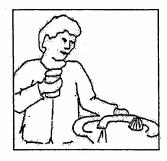
Use a Mycobacteriology (TB) collection kit for all specimen types

Culture Collection of Sputum for Detection of Mycobateria

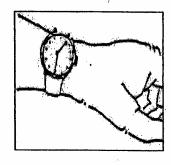




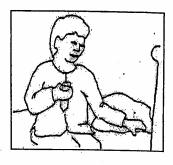
- 1. Use laboratory approved container.
- 2. Collect early morning specimen.



3. Rinse mouth with water.



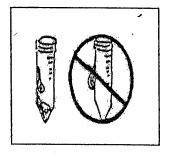
4. Wait at lest 1 minute.



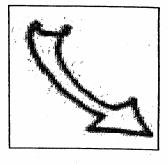
5. Sit on side of bed.



6. Cough deeply and collect any sputum (cold, "flem") brought the up from your chest.



7. Do not get sputum on the outside of the tube. Fill to the 5 ml. mark.



8. Wrap the lab slip around the Metal can and put them in Cardboard can. Tighten the cap securely.

Return samples to the Health Department the same day.

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SPECIMEN COLLECTION FOR CULTURE OF MYCOPLASMA/UREAPLASMA

Principle:

To properly collect a cervical specimen for the culture of Mycoplasma or Ureaplasma

Patient Preparation:

No special preparation.

Supplies:

- 1. Sterile cotton-tipped swab
- 2. Speculum
- 3. Mycoplasma hominis/Ureaplasma transport medium (sent directly from Virology Section) Call 803-896-0819 to obtain
- 4. DHEC form 1335

Collection Precautions:

Wear disposable gloves and protective eyewear when collecting & handling specimens

Collection Procedure: (Cervical)

DO NOT USE SWABS WITH WOODEN SHAFTS TO COLLECT SPECIMEN

- 1. Obtain the cervical specimen with the aid of a speculum that has been moistened with water. Other lubricants may contain antibacterial agents.
- 2. Insert sterile cotton-tipped swab into the endocervical canal approximately 2-3 cm. and swab the cervical OS and the vaginal area. Insert swab into the endocervix only until the cotton tip is no longer visible and rotate gently 10-30 seconds. (Note: if the patient is pregnant, question her about vaginal bleeding or leakage of fluid from the vagina. If either has occurred, DO NOT collect a culture.)
- 3. Place swab in Mycoplasma/Ureaplasma transport medium after collection. Tightly secure the cap of the transport tube to prevent leakage.

Specimen Handling:

- 1. Label a tube of Mycoplasma/Ureaplasma transport medium with a patient label.
- 2. Complete a DHEC 1335 to accompany specimen See instructions on back for completing. Be sure to complete specific test information

Specimen: Mark "X" in the appropriate space. If "Other" is marked, enter site.

Date of Onset: Enter month, day and year.

Symptoms: Mark each symptom that applies. If "Other" is marked, write in symptom(s).

Test Requested: Mark "X" in the appropriate space.

Virus Suspected: Enter name of virus suspected i.e. M. hominis, M. urea or both

Specimen Preservation and Transport:

- 1. If <u>M. hominis</u> is suspected, store in refrigerator and ship with cold packs if specimen will reach the laboratory within six hours. If shipping is delayed beyond 6 hours, freeze at -70°C. and ship on dry ice.
- If Ureaplasma is suspected, specimen can be kept in the refrigerator for 24-48 hours after collection. Ship cold with cold packs. If shipping is delayed beyond 48 hours, freeze at 70°C and ship on dry ice.
- 3. See section IV for appropriate shipping container, packaging and transport instructions.

- 1. Incorrect collection media used
- 2. Specimen not cold on arrival
- 3. Cotton swab with wooden shaft used for collection.
- 4. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF ENTEROVIRUS (STOOL)

Principle:

To properly collect a stool specimen for the isolation of Enteroviruses including Polio, Coxsackie and Echo viruses. Specimens for virus isolation should be collected as early as possible during illness.

Patient Preparation:

No special preparation.

Supplies:

- 1. Wide-mouthed container.
- 2. Tongue depressor
- 3. DHEC form 1335
- 4. Viral Transport media if collecting rectal swab. See page III-1 to order.

Collection Precaution:

WEAR GLOVES WHEN HANDLING ALL STOOL SPECIMENS.

Collection Procedure (Stool)

- 1. Collect stool in a clean (not necessarily sterile) wide-mouthed container that can be covered with a tight-fitting lid. These containers should be free of preservatives and detergents.
- 2. DO NOT COLLECT SPECIMEN FROM TOILET. CONTAMINATION WITH URINE SHOULD BE AVOIDED.
- 3. Infant specimens may be collected in a disposable diaper with plastic side facing inside.
- 4. Collect Solid walnut sized piece if stool is formed. Collect 5-10 ml if stool is liquid
- 5. Place in a dry collection cup. Secure top with tape.

NOTE: If stool cannot be collected, a rectal swab may be collected. Swab should be placed in viral transport medium

Specimen Handling:

- 1. Place a patient identification label on the container.
- 2. Complete a DHEC form 1335 to accompany specimen See instructions on back for completing. Be sure to complete test specific information:

<u>Specimen</u>: Mark "X" in the appropriate space. If "Other" is marked, enter specimen site.

Date of Onset: Enter month, day and year.

Symptoms: Mark each symptom that applies. If "Other" is marked,

write in symptom(s).

Test Requested: Mark "X" in the appropriate space.

Virus Suspected: Enter name of virus suspected.

Specimen Preservation and Transport:

- 1. Store in refrigerator and ship cold with cold packs within 24-48 hours after collection
- 2. If shipping is delayed, freeze at -70°C and ship on dry ice.
- 2. Transport medium is advantageous for virus isolation from swabs.

- 1. Specimen not cold on arrival
- 2. Calcium alginate swab used for collection of rectal swab.
- 3. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF

ENTEROVIRUS, OR RESPIRATORY VIRUS OR MUMPS (THROAT SWAB)

Principle:

To properly collect a throat swab for the isolation of Enteroviruses, Respiratory viruses, or Mumps. (Urine is preferred for Mumps culture.)

Patient Preparation:

No special preparation.

Supplies:

- 1. Sterile cotton or Dacron swab. **Do not use calcium alginate swab**.
- 2. Viral transport media or Influenza transport media (supplied in Influenza kit during flu season or during an outbreak. Store both transport media in refrigerator until needed.
- 3. DHEC form 1335

Collection Procedure for Throat Swab:

Collection of a throat washing has been discontinued because of the use of antibiotics in some collection media

- 1. Shine a bright light if possible over the shoulder of the specimen collector into the oral cavity of the patient so that the swab can be guided to the posterior pharynx.
- 2. The patient is instructed to tilt his/her head back and breathe deeply.
- 3. Depress the tongue with a tongue depressor to help visualize the posterior pharynx.
- 4. Extend the swab to the back of the throat between the tonsillar pillars and behind the uvula.
- 5. Have the patient phonate a long ah which will lift the uvula and help to prevent gagging.
- 6. The tonsillar areas and posterior pharynx should be firmly rubbed with the swab.
- 7. Care should be taken not to touch the teeth, cheeks, gums or tongue when inserting or removing the swab to minimize contamination with normal mouth flora.
- 8. Remove swab and immediately place into:
 - a. Viral transport media for viruses other than Influenza
 - b. Influenza transport media for Influenza

Specimen Handling:

- 1. Place a patient label on vial of viral transport media.
- 2. Complete a DHEC form 1335 to accompany specimen See instructions on back for completing. Be sure to complete test specific information:

Specimen: Mark X in the appropriate space. If Other is marked, enter specimen site.

Date of Onset: Enter month, day and year.

<u>Symptoms:</u> Mark each symptom that applies. If <u>Other</u> is marked, write in symptom(s).

<u>Test Requested:</u> Mark X in the appropriate space.

<u>Virus Suspected:</u> Enter name of virus suspected.

Specimen Preservation and Transport

- 1. Store and ship viral transport tubes cold with cold packs within 24-48 hours after collection.
- 2 Store and ship Influenza transport tubes at room temperature
- 3. See Section IV for appropriate shipping container, packaging and transport instructions.

- 1. Use of calcium alginate swabs.
- 2. Specimen not cold on arrival (if in Viral transport media)
- 3. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CULTURE OF HERPES SIMPLEX

Principle:

The purpose of performing a herpes culture on a genital lesion or cervical/vaginal culture is to diagnose infection with the herpes simplex virus. A positive result is conclusive for diagnosis; however, a negative result does not exclude the diagnosis of herpes. Specimens taken from vesicular fluid are approximately 95% culture-positive; from pustular lesions, 70-85% culture-positive; from ulcers, 70% culture-positive; while only 25% of crusted lesions contain recoverable virus. The duration of viral shedding from ulcerative lesions is longer in first episodes than in recurrent episodes of genital lesions.

Patient Preparation:

No special preparation.

Supplies:

- Sterile cotton-tipped swabs with plastic shafts
 Do Not Use Calcium Alginate Swabs as Herpes Simplex Virus Is Inactivated upon Storage in the Presence of Calcium Alginate.
- 2. Sterile saline (optional)
- 3. Tuberculin syringe with a 26-gauge needle
- 4. Viral transport media. See Page III-1 to order. Store media in refrigerator until needed.
- 5 DHEC form 1335

Collection precautions:

Wear disposable gloves and protective eyewear when collecting and handling specimens.

Collection Procedure: (Genital Lesions, Vesicles and /or Ulcers)

- 1. Clean the surface of the lesion with sterile saline if available or with tap water to remove any contaminating materials such as body fluids, excreta or drainage.
- 2. Specimens should be obtained from active lesions, which include ulcers and vesicular lesions. The younger the lesions, the better likelihood of obtaining a positive culture.
- 3. If the lesions are vesicular in nature, the fluid contained in the lesions can be withdrawn with a tuberculin syringe. The fluid can then be placed into Viral Transport media.
- 4. For vesicles that are intact, open with a sterile cotton-tipped swab.
- 5. Vigorously rub a sterile cotton-tipped swab over the base and margins of the lesion. Obtain vesicular fluid as well as material from the base and margins.Since Herpes viruses are obligate intracellular pathogens, the best way to obtain virus is to collect infected cells which would be present at the base and margins of the lesion.
- 6 Place the swab into transport medium, and break off the end of the swab shaft and leave the swab inside the medium.
- Recap the medium transport tube tightly to prevent leakage during shipment and refrigerate until it is sent to the Bureau of Laboratories.

Collection Procedure: (Cervical)

- 1. Obtain the cervical/vaginal specimen with the aid of a speculum that has been moistened with water.
- 2. Insert the speculum and if unable to visualize the cervical OS, remove excess mucus with a large cotton-tipped swab.

Specimen collection for culture of *Herpes simplex* - page 2 of 2

- 3. Moisten a sterile cotton-tipped swab with transport media and insert the swab into the endocervical canal approximately 2-3 cm and swab the cervical OS and the vaginal area. (NOTE: If the patient is pregnant, question her about vaginal bleeding or leakage of fluid from the vagina. If bleeding or leakage has occurred, DO NOT culture and refer patient to MD. If no bleeding or leakage has occurred, insert swab into the endocervix only until the cotton tip is no longer visible and rotate gently 10-30 seconds).
- 4. Remove the swab and place it into Viral transport medium.
- 5. Rotate the swab in the medium to elute the specimen.
- 6. Break the swab shaft off and recap the medium tightly to prevent leakage
- 7. Refrigerate transport media until transported to the Laboratory.

Specimen Handling:

- 1. Label the transport tube containing swab with a patient label.
- 2. Complete a DHEC form 1335 to accompany specimen. See instructions on back for completing. Be sure to complete test specific information

Specimen: Mark "X" in the appropriate space. If "Other" is marked, enter specimen site.

Date of Onset: Enter month, day and year.

<u>Symptoms</u>: Mark each symptom that applies. If "Other" is marked, write in symptom(s).

<u>Test Requested</u>: Mark "X" by Herpes culture.

Virus Suspected: Enter Herpes

Specimen Preservation and Transport:

Do not freeze at -20 °C. The Herpes virus is sensitive to freezing at this temperature.

1. Place transport tube in a biohazard bag and pack with cold packs in a Styrofoam cooler. Transport within 24-48 hours after collection. If shipping is delayed or a prolonged transit time is anticipated, specimen should be frozen at -70°C and shipped on dry ice.

The herpes virus is relatively unstable and is adversely affected by heat and drying. The titer of virus falls progressively if the transport media reaches room temperature.

- 1. Calcium Alginate swab used for collection
- 2. Specimen not cold on arrival
- 3. Universal rejections, see Section I

SPECIMEN COLLECTION FOR DETECTION OF

HIV-1 ORASURE PROCEDURE

Principle:

To properly collect an oral fluid specimen for the detection of HIV-1.

Patient Preparation:

Have the patient rinse his or her mouth with water prior to collection to avoid food particles or bleeding gums.

Supplies:

- 1. One cotton fiber Collection Pad on a nylon stick
- 2. One Specimen Vial containing Preservative solution.
- 3. DHEC Form 1332

Collection Procedure:

- 1. Peel open Collection Pad package far enough to allow for easy removal. Without touching the contents, present the stick to the test subject and ask them to pull it out of the protective sleeve.
- 2. Instruct patient to place pad between lower cheek and gum and rub back and forth gently until moist.
- 3. Instruct patient to keep the pad in place for 4 minutes (5 minutes maximum), and begin timing.



- 4. Remove the Specimen Collection vial from the package and record test subject identification and date of collection.
- 5. Open vial in upright position (cap up, pointed tip down) by rockin the cap back and forth gently to avoid spilling the contents; give the opened Specimen Vial to the patient, and have them insert the pad the way to the bottom of the vial.



- 6. Instruct the patient to break the pad handle by snapping it agains side of the vial and return the vial to you.
- 7. Replace the cap with a snap.
- 8. Place the Specimen Vial into the sealable bag. Seal the bag and forward to the Bureau of Laboratories for analysis. Take care to avoid extreme changes in temperature after collection of the sample prior to shipment.

SPECIMEN COLLECTION FOR BORDETELLA PERTUSSIS DETECTION BY PCR AND/OR CULTURE

Principle:

To properly collect nasopharyngeal swabs for the detection of *Bordetella pertussis* by PCR. and for culture of the organism.

I. PCR:

Collection Kit* will contain:

2 nasopharyngeal swabs with **Dacron polyester** tips for PCR

1 tube for PCR

1 Request Form (DHEC 1335)

1 instruction sheet

Instructions for collection of NP specimens:

- 1. Insert a thin swab with a flexible wire into the right nare. The swab is introduced flat and then pushed forward with gentle downward pressure on the lower nasal floor to the posterior wall of the nasopharynx. The swab is rotated for a few seconds before it is gently withdrawn. Note: Throat swabs are not acceptable.
- 2. Place the swab into the tube for PCR.
- 3. Repeat steps 1 and 2 for the left nare. Label the tube with the patient's name.
- 4. Complete 1 Bacteriology Request Form (DHEC 1335) to accompany the tubes. Include patient information, date collected, sender name and number, and mark the following boxes:

Specimen Site: Mark "X" in 052 (NP) box **Organism Suspected:** *Bordetella pertussis*

For PCR requests: Write Bordetella pertussis PCR in the Organism Suspected box

If the patient has had antibiotic treatment, please note the drug and when treatment started.

- 5. Transport the PCR swabs on a cold pack in an insulated, crush-proof container. Be sure to include the request form. Send to the attention of Molecular Epidemiology.
- 6. Specimen Preservation and Transport: If shipping is delayed, the PCR tubes can be stored at 4° C. for 24-48 hours.

II. Culture**

Collection supplies needed:

2 nasopharyngeal swabs with **Dacron polyester** tips.

1 tube of Regan-Lowe transport medium***

1 Request Form (DHEC 1335)

Instruction sheet

Instructions for collection of specimens:

- 1. Insert a thin swab with a flexible wire into the right nare. The swab is introduced flat and then pushed forward with gentle downward pressure on the lower nasal floor to the posterior wall of the nasopharynx. The swab is rotated for a few seconds before it is gently withdrawn. Use a second flexible wire swab in the same manner to sample the nasopharynx through the left nare.
- 2. Immediately immerse both swabs into a tube of Regan-Lowe transport medium and <u>tighten</u> the screw cap. The wire shaft of the swab can be bent so that it will fit into the tube. **Note: Regan-Lowe must be at room temperature before the tubes are inoculated.** Write the patient's name on the tube.

3. Complete a Request Form (DHEC 1335). Include patient information, date collected, sender name and number, and mark the following boxes:

Specimen site: Mark 52 Nasopharyngeal Swab **Organism Suspected:** *Bordetella pertussis.* **Test requested:** Mark "X" 510 for culture.

Please indicate any antibiotic therapy the patient has received.

- 4. Place Regan-Lowe transport medium and request form into a double walled mailing container. Address to the attention of Bacteriology. Transport at **room temperature** for overnight delivery to the BOL by the DHEC courier. If shipping is delayed, the Regan –Lowe tube can be incubated at 35° C for 24-48 hours.
 - *For information on submitting specimens for PCR, please contact the DHEC Molecular Epidemiology Laboratory at (803) 896-0824. For kits, please contact the DHEC BOL Materials Logistics Section at (803) 896-0913.
 - ** For information on submitting specimens for culture, please contact the DHEC Bacteriology Laboratory (803) 896-0805.
 - *** For Regan-Lowe transport medium, please contact the DHEC Media/Reagent Section (803) 896-0817.

SPECIMEN COLLECTION FOR CYTOLOGIC EVALUATION BREAST SMEAR

Available only to DHEC County Health Department Clinics

Principle:

These smears are used for the detection of pre-malignant and malignant changes of the breast. This is an effective method for dealing with breast secretions (nipple discharge).

Supplies:

All except the pencil and rubber bands can be obtained from the Bureau of Laboratories See page III-1 to order

- 1. Frosted end slide
- 2. Cyto-spray fixative
- 3. DHEC form 1362, GYN Cytology request form
- 4. Cardboard Slide mailer
- 5. Pencil and rubber bands

Collection Procedure

Drops of fluid from the nipple are smeared directly on clean glass slides and fixed immediately with spray fixative.

- 1. Label the frosted end of a slide with patient's name, ID number, collection date and indicate whether right or left breast.
- 2. Obtain drops of fluid from the nipple and smear them directly on the clean, labeled slide Repeat for second breast if applicable.
- 3. Fix immediately with spray fixative
- 4. After slide(s) are fixed they should be air-dried for about ten minutes before being packaged for transport

Specimen Handling:

Place slide(s) in cardboard slide mailer, close and secure mailer with several rubber bands.

Specimen Packaging and Transport:

- 1. Store and ship at room temperature
- 2. Fixed slides are considered non-hazardous, and do not require special packaging. Package to protect against breakage.

- 1. Slides not fixed, or improperly fixed
- 2. Universal rejections, see Section I

SPECIMEN COLLECTION FOR CERVICAL/ENDOCERVICAL PAP SMEAR

Principle:

To properly obtain a sample of cells from the cervix (Papanicolaou smear) to detect cervical cancer, its precursors, and other abnormalities of the reproductive tract.

Supplies

All except the speculum can be obtained from the Bureau of Labs. See pg III-1 to order.

- 1. Sterilized or single-use disposable bivalve speculum:
- 2. Plastic collection spatula, brush and/or "broom"
- 3. One glass slide with one frosted end
- 4. Cardboard slide mailer
- 5. DHEC form 1362, GYN Cytology request form

Patient Preparation:

Preferably, the woman should be tested 2 weeks after the first day of her last menstrual period and **definitely not when she is menstruating.** Women should not use vaginal medication, vaginal contraceptives, or douches during the 48 hours before the appointment. Intercourse is not recommended the night before the examination.

Collection Precautions:

Cytological specimens should be considered infectious until fixed with a germicidal fixative. OBSERVE UNIVERSAL PRECAUTIONS WHEN COLLECTING AND HANDLING SPECIMENS

Collection Procedure:

1. Position of the Patient:

Although it is possible to perform cervical cytology sampling with the patient in a variety of positions, in the United States it is usually performed with the patient in the dorsolithotomy position.

2. Preparation of the Cervix:

Once the patient is positioned, a sterilized or single-use disposable bivalve speculum of appropriate size should be gently inserted into the vagina, avoiding direct pressure on the sensitive anterior structures (e.g., urethra). Water may be used to lubricate and warm the speculum; however, lubricant jellies should not be used. Several sizes of specula should be available so that an appropriate device may be chosen for the patient. Very young patients, patients with little sexual experience, and elderly patients with vaginal atrophy require the use of a smaller, narrower speculum that women who are sexually active. The speculum must be positioned so that the entire face of the cervix appears at the end of the instrument because a sample from this area is necessary for adequate specimen collection. A large, cotton-tipped swab is often useful for helping to position the cervix.

It is important to obtain a smear that is not obscured by blood, mucus, or inflammatory exudate. Following correct positioning of the speculum in the vagina if there is excess mucus or other discharge present, it should be gently removed with ring forceps holding a folded gauze pad or large, cotton-tipped swab. Inflammatory exudate may be removed by placing a dry 2 X 2-inch piece of gauze over the cervix and peeling it away after it absorbs the exudate, or by using a dry proctoswab or scopette. The cervix should not be cleaned by washing with saline as it may result in a relatively acellular smear. The sample should be obtained before the application of acetic acid.

Cervical/Endocervical PAP smear collections, Page 2 of 5

3. Collection site:

Visual inspection of the lower genital tract and cervix through the speculum is a prerequisite to optimal sample collection. Squamous epithelium of the ectocervix has a smooth, pearly, opaque appearance. Native columnar epithelium of the endocervix is slightly reddish with a "cobblestone" surface. The transformation zone (where native endocervical columnar epthelium has undergone conversion to "immature" metaplastic squamous epithelium) has an intermediate, variegated appearance. (See figure 1.)

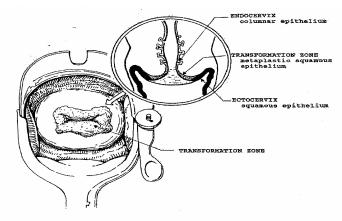
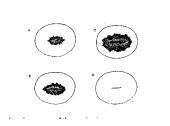


Figure 1. View of the cervix through the speculum

The location and configuration of the active transformation zone is variable, depending on several factors such as vaginal pH, pregnancy, hormonal milieu, menopause, prior therapy, and individual anatomy. The upper (endocervical) limit of the transformation zone is dynamic, defined by the leading edge of the migratingsquamo-columnar junction. In postmenopausal women, the squamo-columnar junction is often high in the endocervical canal and no longer visible. (See Figure 2.)

Figure 2: Variations in cervical mucosa

- A. Narrow transformation zone
- B. Broader transformation zone
- C. Broadly everted transformation zone- parous type.
- D. Squamo-columnar junction high in Endocervical canal-postmenopausal or post-treatment type



An optimal cervical specimen includes sampling of the squamous and columnar epithelium, encompasing in particular the transformation zone where the majority of cervical neoplasias arise. The specific sampling instrument(s) and sampling technique used should be based on a consideration of individual patient anatomy, particularly the location and configuration of the transformation zone as determined by visual inspection. The method detailed below outlines a collection technique using a combination of wooden or plastic spatula and cervical brush instruments.

4. Collection Procedure Using Wooden or plastic spatula and Cervical Brush*

(a) Slides should be labeled before the smear is obtained.

Label frosted end of the glass slide with the patient's first and last name, as well as date of birth, using a diamond or hard (#3) lead pencil. (inks tend to run in processing.) If the specimen consists of more than one slide, it is mandatory that the source of the specimen be indicated.

PAP smear Collection, page 3 of 5

- (b) **Observe universal precautions for collecting and handling specimens** Insert the speculum, which may be *slightly* moistened with water or saline. No other lubricants should be used.
- (c) Visually identify the cervix, and the transformation zone, if visible, and direct sampling efforts to encompass this area. **Note:** If an elevated, ulcerated, necrotic, or exudate-covered lesion is observed, arrangements should be made for <u>biopsy</u> following cytology sampling.
- (d) Choose the contoured end of the spatula that best conforms to the anatomy of cervix in the transformation zone. Rotate spatula at least 360° about circumference of the Cervical os and ectocervix, while maintaining firm contact with the epithelial surface.

Note: A clockwise rotation beginning and ending at 9 o'clock (or counter-clockwise rotation from 3 o'clock to 3 o'clock) will position the spatula so that the collected material is retained on the upper horizontal surface as the instrument is removed.



Do <u>not</u> smear the sample at this time unless the specimen is to be immediately fixed (see 3-B) Hold the spatula between the fingers of the nonsampling hand (or rest it on the glass slide) with the specimen face-up, while the cervical brush material is collected without delay.

(e) Insert the cervical brush into the os: Some bristles should still be visible. This will minimize inadvertent sampling of the lower uterine segment.

With *Gentle* pressure, rotate the brush only 90 to 180 ° to minimize bleeding..

Note: Brushes have circumferential, radiating bristles that come in contact with the entire surface of the os upon insertion. This is in contrast to the edge of a spatula which is in contact with only a fraction of the epithelial surface at any one time. Therefore, the brush need only be rotated one quarter turn (90°) while the spatula must be rotated at least one full turn (360°).

*The use of both instruments is recommended for optimal sampling. The preferred order of spatula and brush sampling has not been subjected to large scale studies. Obtaining the spatula specimen first diminishes the possibility of blood contamination due trauma by the brush. However, some speculate that performing the brush collection first may increase the yield of exfoliated abnormal cells by the spatula. One option is to sample the ectocervix twice, both before and after obtaining the endocervical brush specmen.

Above figure: The solid black area represents mature squamous epithelium, the hatched area represents the transformation zone, and the stippled area the original endocervical zone

Prepare Smears:

The object is to quickly but evenly spread the cellular material in a thin layer on the glass slide. Thin out large clumps of material as much as possible, while avoiding excessive manipulation, which can damage cells. To avoid the development of air-drying artifact, transfer the material from both sampling instruments to the material from both sampling instruments to the slide within a few seconds and fix immediately.

Cervical/ Endocervical PAP smear Collection, Page 4 of 5

- To transfer material from the spatula, smear the sample with a single stroking motion using moderate pressure to thin out clumps of cellular and mucus material. Avoid excessive force or manipulation, which will damage cells.
- 2. To transfer material from the brush, roll the bristles across the slide by twirling the brush handle.
- 3. To transfer material from the broom, smear the sample with a painting action, using both sides of the broom.

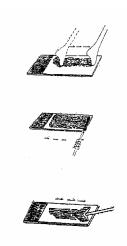


Figure 4. Transferring the sample to the slide

- Smearing option A
 Smear the spatula sample across the slide:
 Roll the brush directly over top and Fix immediately.
 (with this method, the ability to localize the origin of the cells may be lost.)
- 5. Smearing option B
 Spread the spatula sample over the left side of the slide, cover the right-hand side with cardboard, and immediately spray fix
 Roll the brush material onto the right-hand side of the slide and immediately spray fix
 Note: With this method, the spatula specimen may be spread and fixed before obtaining the endocervical brush sample.

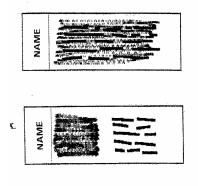


Figure 5. Options for transferring the samples to glass slides

Fix smears

After the specimen has been spread evenly on the slide, the slide should be fixed <u>immediately</u>. Fixatives are agents that are used on gynecologic smears to prevent cell distortion and to maintain true morphologic structure. Distortion due to improper fixation nearly always prevents proper and accurate evaluation of the cell population. Air drying is the absence of fixation. Air drying produces artifacts and cellular distortion and may lead to misinterpretation of smears. Air drying of a Pap smear is **NOT** recommended.

1. Cytofixative spray is the recommended fixative and is provided upon request
Hold the nozzle of the cytofixative spray can approximately 12 inches from the slide, and
apply an even coat to cover the smeared area. Holding the spray fixative container too close
to the slide can result in the development of cellular artifacts, while holding the container
too far from the slide may result in drying artifacts or uneven fixation Holding the spray
fixative too close to the slide can also result in flooding the slide and washing or blowing
away the cells.

The use of commercially available hairspray is a common practice in some parts of the country. Use of this material is absolutely discouraged because of the variability in the ingredients. (These cosmetic aerosols may result in a very poor specimen preservation.)

Specimen collection for Cervical/Endocervical PAP smear, page 5 of 5

2. Alternative Wet Fixation with 95% ethanol

A widely accepted, ideal cellular fixative for gynecologic/cytologic smears is 95% ethanol. Place 95% ethanol in an appropriate container and immerse the freshly prepared smear immediately into the fixative. Fixation occurs in 5 to 30 minutes. If the fixative is to be reused, it should be filtered.

Specimen Handling

- 1. Allow slides to dry completely before packaging for transport.
- 2. Complete a DHEC form 1362 to accompany the specimen See general instructions for completing, Pg III-3. Be sure to complete specific test Information.

Date of collection

Date of LMP

Specimen source

Provider code

Specimen Transportation:

- 1. Place properly labeled slides in cardboard slide mailer transport to prevent breakage.
- 2 Fixed slides are considered non-hazardous and do not require special precautions while transporting.

- 1. Smears improperly prepared or fixed
- 2. Universal rejections, see Section I

SPECIMEN COLLECTION FOR DETECTION OF

CHLAMYDIA/GC GEN-PROBE APTIMA COMBO 2 PROCEDURE

Principle:

To properly collect a specimen for the detection of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

Patient Preparation:

See collection procedures below

Supplies:

- 1. GC/ Chlamydia Gen-Probe supplies See page III-1 to order.
- 2. Unisex Collection Kit. Use blue swab only for collecting both male and female specimens.
- 3. DHEC form 1332

Collection Procedure for Endocervical Swab Specimens:

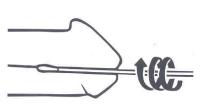
- 1. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in package with red printing). **Discard this swab.**
- Insert specimen collection swab (blue shaft swab in package with green printing) into endocervical canal.
- 3. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
- 4. Withdraw swab carefully; avoid any contact with vaginal mucosa.
- 5. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- 6. Carefully **break swab shaft at scoreline**. Use care to avoid splashing contents.
- 7. Re-cap swab specimen transport tube tightly.
- 8. See Specimen Transport and Storage below.

Collection for Male Urethral Swab Specimens:

Patient should not have urinated for at least 1 hour prior to collection.

- 1. Insert specimen collection swab (blue shaft swab in package with green printing) 2-4 cm into urethra.
- 2. Gently rotate swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling.
- 3. Withdraw swab carefully
- 4. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen collection tube.
- 5. Carefully **break swab shaft at scoreline**. Use care to avoid splashing contents.
- 6. Re-cap swab specimen transport tube tightly.
- 7. See Specimen Transport and Storage below.



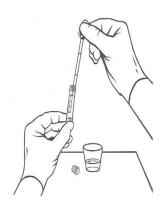


GC/CT Gen-Probe Collection, page 2 of 2

Collection for Male and Female Urine Specimens

Patient should not have urinated for at lease 1 hour prior to specimen collection.

1. Direct patient to provide first-catch urine (approximately 20 to 30 ml of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.





- 2. Remove cap from urine specimen transport tube and transfer 2 ml of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.
- 3. Re-cap urine specimen transport tube tightly. This is now known as the "processed urine specimen."
- 4. See *Specimen Transport and Storage* below.

Specimen Handling:

Complete DHEC form 1332 to accompany specimen See instructions on back for completing.

Be sure to complete test specific information.

Specimen Preservation and Transport

A. Swab

- 1. After Collection, transport and store swab in swab specimen transport tube at 2°C to 30°C until tested.
- 2. Specimens must be assayed with the GEN-PROBE APTIMA Combo 2 Assay within 60 days of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 90 days after collection.

B. Urine

- 1. After collection, transport the processed urine specimens in the GEN-PROBE APTIMA Combo 2 Assay urine specimen transport tube at 2°C or 30°C and store at 2°C or 30°C until tested. Processed urine specimens should be assayed with the APTIMA Combo 2 Assay within 30 days of collection. If longer storage is needed, freeze at -20°C -or-70°C for up to 90 days after collection.
- 2. Urine samples that are still in primary collection container must be transported to lab at 2°C or 30°C. Transfer urine sample into APTIMA Combo 2 Assay urine specimen transport tube within 24 hours of collection. Store at 2°C or 30°C and test within 30 days.
- 3. See section IV for appropriate shipping container, packaging and transport instructions

Specimen Rejection:

- 1. No swab in tube, 2 swabs in tube, or improper(non blue) swab used
- 2. Specimen other than urine or genital
- 3. Universal rejections, see Section I

Note: Specimens collected with this system cannot be used for culture. Only swabs supplied with the Gen-Probe specimen collection system should be used for specimen collection.

SPECIMEN COLLECTION FOR OVA AND PARASITES

Principle:

To properly collect a stool specimen for the detection of intestinal parasites such as Giardia, Cryptosporidia, Microsporidia, Cyclospora, or helminth eggs and larvae i.e. Ascaris, hookworms, tapeworms.

Patient Preparation:

No special Preparation

Supplies:

- 1. Parasitology kit (O & P) See page III-1 to order.
 - Note: This kit will not allow detection of trophozoites.
- 2. PVA preservative for liquid stools and detection of trophozoites (Not provided)
- 3. DHEC form 1335
- 4. 10% formalin (recommended for parasites such as Cyclospora) (Not provided)

Collection Procedure:

Refer to diagram that follows.

- 1. Have patient produce a bowel movement in a clean wide-mouthed container or on a clean paper. DO NOT COLLECT SPECIMEN FROM TOILET.
- 2. Infant specimens may be collected in a disposable diaper by turning the diaper inside out with the plastic side facing the skin. Specimens collected on the absorbent side are not acceptable.
- 3. Fill plastic tube ½ full with feces. Screw cap on tightly.

 If using PVA or 10% formalin, place feces in preservative immediately after collection.

 Most commercially prepared preservatives have a "fill line" on the container to indicate the quantity required. Follow manufacturer's instructions.

Specimen Handling:

- 1 Place a patient identification label on the outside of the plastic tube.
- 2. Place plastic tube into the metal can. Screw cap tightly.
- 3. Complete a DHEC form 1335 to accompany specimen See instructions on back for completing. Be sure to complete test specific information:

Organism Suspected: Indicate organism suspected.

<u>Test requested</u>: Mark X in the appropriate space.

Specimen Preservation and Transport:

- 1. Wrap request form around the metal can containing the specimen. Place both into the cardboard container. Screw cap tightly.
- 2. Store and ship at room temperature to arrive within 4 days after collection.
- 3. See section IV for appropriate shipping container, packaging and transport instructions

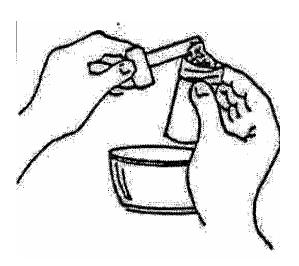
- 1. Specimen contaminated with urine or water, laxatives or barium
- 2. Specimen covered in fungal growth
- 3. Specimen more than 4 days old
- 4. Universal rejections, see Section I

STOOL COLLECTION FOR OVA AND PARASITES

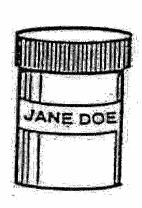
This kit is for detection of cyst forms. Detection of trophozoites requires submitting the specimen in a preservative such as PVA (polyvinyl alcohol). Liquid stools are more likely to contain trophozoites and should be submitted in a preservative.

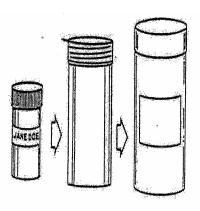
- 1. Have patient produce a bowel movement (number two) in a clean container or on a newspaper.
- 2. Fill the plastic tube ½ full with bowel movement. Screwcap on Tightly.





- 1. Print patient's name on the label of the plastic tube. Please keep outside of the tube clean.
- 4. Put plastic tube into the metal can. Screw cap tightly. Wrap the request form around the metal can. Place both into the mailing container





5. Return the kit to the Health Department as soon as possible or bring to the Bureau of Laboratories at 8231 Parkland road, Columbia, SC. Specimens more than 2 days old may not yield accurate results.

SPECIMEN COLLECTION FOR PINWORM PREP

Principle:

Diagnosis of Pinworm infection can be confirmed by the demonstration of *Enterobius vermicularis* ova in the perianal area.

Patient Preparation:

No special preparation.

Supplies:

- 1. Pinworm Prep. Slide
- 2. Cellulose (scotch) tape strip. Use clear tape. *Do Not use frosted tape*.
- 3. Clean microscope slide
- 4. Tongue depressor
- 5. Slide label
- 6. Slide mailing container
- 7. DHEC form 1335

Slide Preparation:

Place strip of cellulose tape to cover slide, folding back approximately ½ inch piece on one end to form a tab.

Collection Procedure:

Best time for collection is a few hours after retiring, first thing in the morning before bowel movement or both. Therefore, collection is usually done at home.

- 1. Instruct patient or parent in collection procedure. (See illustration that follows.) Give prepared slide, collection diagram and mailing container to patient or parent
- 2. Instruct patient/parent on packaging and shipping of specimen to the laboratory.

Specimen Handling:

- 1. Label slide with patient's name
- 2. Complete DHEC form 1335, to accompany specimen

See instructions on back for completing

Be sure to complete specific test information:

Reason for test: Mark X in the appropriate box Test required: Mark X in the appropriate space

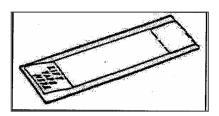
Specimen Preservation and Transport:

- 1. Place slide(s) in cardboard slide mailer
- 2. Secure mailer with rubber band and place in biohazard bag
- 3. Store and ship at room temperature.
- 4. See section IV for appropriate shipping container, packaging and transport.

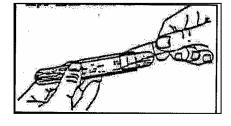
- 1. Frosted tape used
- 2. Universal rejections, see Section I

PINWORM PREP

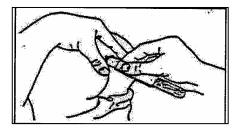
Use of cellulose tape slide for pinworm collection



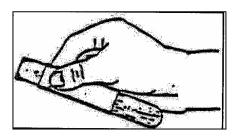
1. Cellulose-tape slide preparation



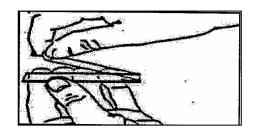
 Hold slide against tongue depressor one inch from end of depressor.
 Lift tape from slide



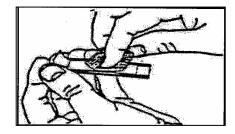
3. Loop tape over end of tongue depressor sticky side out and press tape to anal region to cover as much of the perianal area as possible



4. Hold tape and slide against tongue depressor



5. Loosen end of tape from end of depressor and press tape onto slide, sticky side down Apply the tape so as to prevent trapping air bubbles between tape and slide



6. Use cotton or gauze to smooth tape down

Note: Best time for collection is a few hours after retiring (10 or 11 pm) or first thing in the morning before bowel movement.

SPECIMEN COLLECTION OF SKIN SCRAPINGS FOR SCABIES

Principle:

Diagnosis of scabies can be confirmed by demonstration of the mites, eggs or scybala (fecal pellets). Because the mites are located under the surface of the skin, scrapings must be taken from the infected area.

Supplies:

- 1. Mineral oil
- 2. Sterile scapel blade
- 3. Clean glass slide and coverslip
- 4. Applicator stick
- 5. DHEC form1335
- 6. Cardboard slide mailer (holds 2 slides)
- 7. Biohazard bag

Safety Precautions:

Specimens must be handled with care. *Sarcoptes scabei* is highly contagious. Wear gloves and lab coat while collecting specimens.

Collection Procedure:

- 1. Place a drop of mineral oil on a sterile scalpel blade. (Mineral oil is preferred over potassium hydroxide solution or water. Mites will adhere to the oil and oil will not dissolve fecal pellets).
- 2. Allow some of the oil to flow onto the papule.
- 3. Scrape vigorously six or seven times to remove the top of the papule. (There will be tiny flecks of blood in the oil).
- 4. Transfer the oil and scraped material to a glass slide. (An applicator stick can be used).
- 5. Add **one or two drops** (no more than 2) of mineral oil to the slide and stir the mixture.
- 6. Place a cover slip on the slide.

Specimen Handling:

- 1. Place a patient identification label on the edge of the glass slide
- 2. Complete DHEC form 1335 to accompany specimen. See instructions on back for completing.

Specimen Preservation and Transport:

- 1. Place slide(s) in cardboard slide mailer. or plastic slide box (not supplied)
- 2. Secure mailer with rubber band and place mailer in Biohazard bag.
- 3. Store and ship at room temperature
- 4. See section IV for appropriate shipping container, packaging and transport instructions.

- 1. Too much oil used (more than 2)
- 2. Universal rejections, see Section I

URINE DRUG SCREEN SPECIMEN COLLECTION AND CHAIN-OF-CUSTODY PROTOCOL

Principle:

To properly collect a urine specimen for forensic urine drug testing

A chain-of-custody (COC) protocol must be maintained for the urine specimens. Chain-of-custody is a protocol used to certify that a sample has not been compromised.

Supplies:

- 1. Collection Containers w/lids
- 2. Security Tapes
- 3. Permanent Ink Marking Pens
- 4. Temperature Strips
- 5. Tamper-proof Bio-Hazard Bags
- 6. Integrity Seals
- 7. Mailing label for outside of box
- 8. DHEC form 1310, Forensic Urine Drug Testing (chain of custody)

Collection Preparation:

1. Complete DHEC form 1310, Forensic Drug Testing (blue) to accompany each specimen. All patient and sender information on the top half of the form (except the temperature box) as well as the Patient History box must be completed by the collector **prior to specimen collection** See general instructions for completing, page III-3. Be sure to complete Test specific information and Patient history.

Date and time specimen collected

<u>Type of Specimen</u>. Mark X in appropriate box. **Medical** samples are not automatically confirmed. The client must request this confirmation testing.

Reason for Test: Mark X in appropriate box.

<u>Test Requested</u>: Mark X in appropriate box.

<u>Patient History:</u> List any medications (prescription and over the counter) the donor is currently taking or has taken in the past 2 weeks. **Inform the donor that this information is voluntary.**

2. Write Donor's name (must exactly match name on form) and date collected on the side of the collection cup. It is not necessary to write anything on the lid.

Collection Procedure:

- 1. Prepare toilet area: Remove all chemicals or cleaning supplies from the collection area
 Tape flush handle of toilet and any water faucets in area closed.
 Put dye or food coloring in toilet bowl (Red preferred)
- 2. Instruct donor that they will not be allowed to carry any personal items into the collection
- 3. Attach a temperature strip on the side of the collection container near the base. Give container, but NOT the lid, to the donor and instruct donor to provide at least 30 ml. of urine. Any specimen of less than 30 ml. will be rejected for Chain-of-Custody. If donor cannot provide the minimum quantity, the specimen will be discarded and the donor will be required to provide another specimen later using a clean container. Donor may be allowed to drink fluids to stimulate urine production.
- 4. The donor must return the container with specimen to collector within 4 minutes collection.

Specimen Handling

The Collector & the Donor Must Keep the Specimen in View at All Times

1. The collector will close the container **in the presence of the donor** by tightly screwing the lid in a clockwise direction. Be sure lid is not canted to prevent leakage during transport.

Urine Collection for Drug Screen, Page 2 of 2

- 2. Collector will note the Temperature (green area on specimen collection temperature strip) and complete the Temperature box of the request form. It is critical to check the temperature of the specimen within 4 minutes from collection.
 - a. Mark X to indicate if temperature was read within 4 minutes
 - b. Mark X in Yes box if temperature is within acceptable range(90.5 to 99.8°F). If the temperature of the urine is not within this range, it is not acceptable and another specimen must be collected immediately.
 - c. Record the actual temperature. (not required but is used for informational purposes)
- 3. Collector will seal the container in the presence of the donor with security tape and both must initial the tape. Be sure that tape has collection date. Do not cover the writing on the side of the container. One unbroken strip over the top and down the sides of the container is sufficient to maintain COC requirements.
- 4. Donor must review the testing form for accuracy of information. If there is an error it will be corrected as follows:
 - a. Information entered by collector will be corrected by collector. Information entered by donor will be corrected by donor.
 - b. Mark through the incorrect information with **ONE single line**. Date and initial the marked thru line. Insert the correct information above or to the side of the marked thru line.
- 5. The collector should then read the certification statement to the donor and have him/her place his/her signature and the current date on the line marked "Donor Signature and Date". The collector should sign his/her name on the line marked "Collector's name and Date. If the form is missing either signature or date, the specimen must be rejected.
- 6. After completing this section, give the donor the back copy (part 4, donor copy) and remind donor to retain it in a secure place for their files.
- 7. Place the specimen into the smaller pouch of the Tamper-proof biohazard bag. Seal the bag before the donor leaves.
- 8. At this point, collection is complete and **Donor is free to leave.**

Failure to comply with the above protocol will result in loss of Chain-of Custody verification. The specimen will be tested as a NON chain-of custody specimen.

Specimen Preservation and Transport:

- 1. Place a paper towel and specimen into the bio-hazard bag to absorb any leakage.
- 2. Tear off the original and first copy of the DHEC 1310 form, fold and place inside the outside pocket of the bio-hazard bag. **Do not place the form inside the bag with specimen**. The remaining copy is for the employer (collector) to keep.
- 3. Use the smallest box which will accommodate the number of specimens you are transporting. Place the specimen(s) into the shipping container with newspaper or paper towels around the bio-bag(s) to minimize movement of specimens during transport.
- 4. Seal the shipping container with tape, stretching it across the top of the two flaps and extending down sides of box.
- 5. Place Toxicology label and Integrity Seals (yellow labels) on the outside of the shipping box so they bridge the two flaps of the shipping container.
- 6 DO NOT use a biohazard sticker on the outside of the shipping container.
- 7. Transport at room temperature.

Specimen Rejection:

- 1. Specimen volume is not at least 30 ml.
- 2. Form is not filled out and signed as required.
- 3. No date and/or initials on security tape.
- 4. Evidence of tampering with the mailing box or specimen.

Transporting and Shipping Infectious Substances and Diagnostic Specimens (Updated January 2, 2006)

Patient specimens and infectious substances <u>must be properly packaged and labeled to</u> protect the employees transporting and receiving the materials.

A few types of materials sent for diagnostic testing, such as pap smears and newborn screening blood spots, have unique properties and do not ship under the full requirements of most diagnostic specimens. To ship pap smears or newborn screening blood spots follow the information below.

Shipping Fixed Microscope Slides and Newborn Screening Blood Spots

Shipping Microscope slides:

Once pap smear slides are fixed, the slides are no longer considered infectious and do not meet the definition of an infectious material. To ship microscope slides, take the following steps:

- 1. Place slides into the cardboard slide holder.
- 2. Wrap the lab form around the closed slide holder and secure with a rubber band around the slide holder and lab form.
- 3. Place the slide holder in a manila envelope addressed to:

DHEC Bureau of Laboratories Attn. Specimen Accessioning 8231 Parklane Road Columbia, SC 29223

4. Ship by state courier or first class US Mail. No additional labeling is required on the outside of the envelope. The slides are not considered infectious materials.

Shipping Newborn Screening Blood Spots

- 1. Allow blood spots to **AIR DRY** thoroughly on a level non-absorbent surface such as a plastic coated test tube rack at least 4 hours at room temperature.
- 2. Place **dried** filter paper form(s) into the provided mailing envelope. Mail the specimen within 24 hours. No additional labeling is required on the outside of the envelope. The dried blood spots cannot leak or spill.
- 3. Ship by state courier or first class US Mail. No additional labeling is required on the outside of the envelope.

Shipping Infectious Substances and Diagnostic Specimens

The International Air Transport Association (IATA) classification system for shipping infectious substances changed on January 1, 2005. There were also some changes in the marking and labeling requirements. The US Department of Transportation (DOT) published a proposed rule on May 19, 2005 to harmonize the DOT regulations with the changes made by IATA (United Nations Recommendations). The US Postal Service plans to bring their regulations into alignment with IATA; proposed changes will be published in the spring of 2006. Risk groups are no longer used to determine the proper shipping category for infectious substances. The following definitions are now used.

IATA Definitions:

CULTURES: Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient specimens as defined in 3.6.2.1.4.

DANGEROUS GOODS: Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in theses Regulations or which are classified according to the Regulations.

INFECTIOUS SUBSTANCES: Substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

PACKING: The art and operation by which articles or substances are enveloped in wrappings and/or enclosed in packaging or otherwise secured.

PATIENT SPECIMENS: Patient specimens are those human and animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

PROPER SHIPPING NAME: The name to be used to describe a particular article or substance in all shipping documents and notifications and, where appropriate, on packaging.

SHIPMENT: The specific movement of a consignment from origin to destination.

UN NUMBER: The four digit number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods to identify a substance or a particular group of substances. (The prefix "UN" must always be used in conjunction with these numbers.)

Classifying Infectious Substances

Infectious substances are divided into 2 categories – A and B.

Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in Table 3.6.D.

Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373.

As a general rule, all cultures will be in category A and most body fluids and tissue will be in category B. A swab placed in a genprobe bottle would not meet the IATA definition of a culture and would be shipped as a diagnostic specimen.

Table 3.6.D (pages 4 & 5) was developed as a guidance document to give examples of infectious agents that should be classified as category A regardless of the type of specimen.

Note: This table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to category A.

Table 3.6.D from IATA Dangerous Goods Regulations Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicted (3.6.2.2.2.1) (Updated 1-1-2006)

UN Number and	(5.0.2.2.2.1) (opdated 1 1 2000)
Proper Shipping Name	Micro-organism
UN 2814	Bacillus anthracis (cultures only)
Infectious substance	Brucella abortus (cultures only)
affecting humans	Brucella melitensis (cultures only)
	Brucella suis (cultures only)
	Burkholderia mallei - Pseudomonas mallei - Glanders (cultures only)
	Burkholderia pseudomallei - Pseudomonas pseudomallei (cultures only)
	Chlamydia psittaci - avian strains (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxiella burnetii (cultures only)
	Crimean-Congo hemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	Escherichia coli, verotoxigenic (cultures only)
	Ebola virus
	Flexal virus
	Francisella tularensis (cultures only)
	Guanarito virus
	Hantaan virus
	Hantavirus causing hemorrhagic fever with renal syndrome
	Hendra virus
	Hepatitis B virus (cultures only)
	Herpes B virus (cultures only)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Marburg virus
	Monkeypox virus
	Mycobacterium tuberculosis (cultures only)
	Nipah virus
	Omsk hemorrhagic fever virus
	Poliovirus (cultures only)
	Rabies virus (cultures only)
	Rickettsia prowazekii (cultures only)
	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)

	Sabia virus				
	Shigella dysenteriae type 1 (cultures only)				
	Tick-borne encephalitis virus (cultures only)				
	Variola virus				
	Venezuelan equine encephalitis virus (cultures only)				
	West Nile virus (cultures only)				
	Yellow fever virus (cultures only)				
	Yersinia pestis (cultures only)				
UN 2900	African swine fever virus (cultures only)				
Infectious substances	Avian paramyxovirus Type 1 - Newcastle disease virus (cultures only)				
affecting animals	Classical swine fever virus (cultures only)				
	Foot and mouth disease virus (cultures only)				
	Goatpox virus (cultures only)				
	Lumpy skin disease virus (cultures only)				
	Mycoplasma mycoides - Contagious bovine pleuropneumonia (cultures				
	only)				
	Peste des petits ruminants virus (cultures only)				
	Rinderpest virus (cultures only)				
	Sheep-pox virus (cultures only)				
	Swine vesicular disease virus (cultures only)				
	Vesicular stomatitis virus (cultures only)				

Examples of shipping categories

Material	Infectious Substance, category A	Infectious Substance, category B
Culture of HIV virus	X	
Tube of blood from a HIV + person		X
Tube of blood from a person infected with Bacillus anthracis		X

Proper Shipping Names and UN Numbers

Once an infectious material has been classified, then the proper shipping name must be determined. The proper shipping name is required on the outer packaging. The UN number must also be on the outside packaging for infectious substances, category A. If transport is by air, the UN number must be on the outside packaging for infectious substances, category B (diagnostic specimens). The table below lists the proper shipping names and UN numbers needed to ship infectious substances and diagnostic specimens.

Proper Shipping Names

(from IATA Dangerous Goods Regulations, effective 1 January – 31 December 2006, 4 2 List of Dangerous Goods)

Classification	Proper shipping name	UN number
Infectious substance,	Infectious substance, affecting	UN 2814
Category A (infects humans	humans	
& may infect animals)		
Infectious substance,	Infectious substance, affecting	UN 2900
Category A (only infects	animals	
animals)		
Infectious substance,	Diagnostic Specimen or	UN 3373
category B	Clinical Specimen or	
	Biological Substance, Category B	
	[Note: From 1 January 2007, it is	
	anticipated that the use of the	
	shipping names Diagnostic	
	specimens and Clinical specimens	
	will no longer be permitted.]	

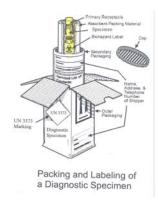
Packing Infectious Substances for Transport

All packaging is based on a "triple" receptacle shipper.

- Infectious substances, category A, must be packaged to meet packing instruction **602**.
- Infectious substances, category B (Diagnostic specimens) must be packaged to meet packing instruction **650**.

A primary receptacle is the container (e.g., tube vial, bottle) that holds the specimen.

- The primary receptacle must be securely sealed and leak proof (screw top tubes must have a piece of waterproof tape around the top to prevent the top from coming loose in transit).
- The primary receptacle must be surrounded by absorbent material capable of taking up the entire liquid contents.
- The primary receptacle must be packed in the secondary receptacle in such a way that it will not break.



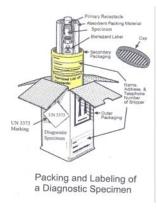
• IATA regulations allow 1 liter in a primary receptacle for diagnostic specimens. The outer packaging must not contain more than 4 liters.

NOTE: Most DHEC shippers are designed for a **maximum of 50 ml** of liquid diagnostic specimens. Remember, there must always be adequate absorbent materials to absorb the amount of liquid in a primary receptacle.

<u>Secondary packaging</u> is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed.

- The secondary packaging must be leak proof and securely sealed.
- The secondary packaging must be placed in the outer packaging so that it does not move.

Note: A ziplock biohazard bag may serve as the secondary receptacle for a diagnostic specimen if transport is by ground with the state courier system.



Itemized List of Contents

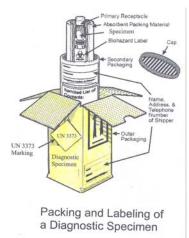
- An itemized list of contents is required.
- The itemized list is placed OUTSIDE the secondary container. The laboratory form should also be placed OUTSIDE the secondary container.
- DO NOT place documents inside the secondary container.

Itemized List used by the Bureau of Laboratories

Shipped from:	SC DHEC Bureau of Laboratories 8231 Parklane Road Columbia, SC 29223 Emergency Contacts: Connie Gray or Dr. Arthur Wozniak Emergency Telephone: (803) 896-0800	
Shipped to:		
Shipping Temper: ambient cold packs dry ice	Next day delivery required No Yes	
temized List of C	ontents (list name of organism when known, list amount)	

<u>Outer packaging</u> is the receptacle into which the secondary receptacle, along with cushioning materials, are placed.

- The outer packaging must be rigid (effective 1-1-2005).
- The outer packaging bears the addressing information along with all required markings and labels. The full name and address of the shipper and the consignee must be on the outside packaging. The outside packaging must also have the name and telephone number of a person who is knowledgeable about the contents of the shipment. This is important emergency information in the event an exposure occurs during shipping.



- For air transport, at least one surface of the outer packaging must have a minimum dimension of 4 inches x 4 inches.
- For air transport of diagnostic specimens, a UN 3373 marking must be on the outside receptacle. The words "Diagnostic Specimen" must be marked on the outer package adjacent to the diamond-shaped UN 3373 marking.

Note - Only the words "Diagnostic Specimen" are required for packages in the state courier system and the US Postal Service at this time.

Note - Do not place biohazard stickers on the outside container. The biohazard marking should be on the secondary receptacle and may be on the primary receptacle.

• If a "Shippers' Declaration for Dangerous Goods" is required, the document is attached to the top of the outside packaging.

For diagnostic specimens, the completed package must be capable of successfully passing a drop test of 1.2 meters. If transport is by air, the completed package must pass a pressure test.

Additional Requirements for Infectious Substance, Category A
Packaging

- Packaging must be UN certified (this means the packaging unit has passed drop, impact and pressure tests)
- The UN Certification number must be printed on the outside container.
- UN Certified Packaging must be used as a complete shipping package as received from the manufacturer. Substitution of parts of the packaging with other manufacturer's shipping materials is not allowed.
- Maximum quantity per shipper is 50 ml or 50 grams on passenger aircraft and 4 liters on cargo aircraft.
- The Class 6 Infectious Substance label must be on the outside packaging.
- The proper shipping name and UN number must be on the outside packaging. Adjacent to this information the net quantity of infectious substance in the package must be shown. Effective January 1, 2005, for security purposes, the name of the organism is no longer required on the outside packaging. However, the name of the organism is still required on the "Shipper's Declaration For Dangerous Goods".
- Documentation the material was received (email, USPS return receipt, tracking number showing receipt, etc.) along with a copy of the "Shippers' Declaration for Dangerous Goods must be kept for 375 days.
 NOTE: Federal Aviation Administration (FAA) Inspectors refer to this documentation as your 375 day file.
- Most packaging for cultures of infectious substances is designed to hold screw-top tubes. If possible, ship the culture on an agar slant in a screw-top tube. Tape around the screw top with autoclave tape to prevent the top from working loose

during shipment. If culture plates must be shipped, ensure the packaging set-up will accommodate and protect a culture plate. Culture plates should always be taped closed and placed in a zip lock bag as the first step in packaging.

Shippers Declaration of Dangerous Goods

The "Shipper's Declaration For Dangerous Goods" is a legal document. If it is not 100% correct, it is **WRONG** and your package will be refused for shipment and returned.

- A "Shippers Declaration of Dangerous Goods" is **not** required for diagnostic specimens.
- A "Shippers Declaration of Dangerous Goods" is required for infectious substances, category A by commercial carriers.



Note – The state courier does not require a "Shipper's Declaration for Dangerous Goods". This is one very good reason to use the state courier system.

- The document must be attached to the top of the package in a ziplock bag
- The document must be completed in **triplicate**, each as an original, with the red stripe down each side of the paper. Two copies are given to the transporter and one copy is kept for your files.

Note - The format of the "Shippers Declaration For Dangerous Goods" will change on January 1, 2007. In the "Nature and Quantity of Dangerous Goods" section, the UN number will be the first column. The revised document may be used now, but will be required on January 1, 2007.

The Shippers Declaration For Dangerous Goods may be completed on line at http://www.fedex.com/us/services/pdf/ShippersDecColumnsColorPrinter.pdf?link=4 and printed on a color printer.

Examples of completed "Shippers' Declaration for Dangerous Goods" are found at the end of this document.

Shipping Temperatures

Check the test section in the *Bureau of Laboratories Services Guide*, if unsure of temperature requirements for the infectious substance being shipped.

- If the specimen must be shipped cold, but not frozen, use cold packs. Ice will melt
 and leak during shipping.
 [NOTE: All diagnostic specimens shipped for PCR testing should be shipped
 cold.]
- If the specimen must be shipped frozen, additional labeling is required for dry ice.

Labeling and Marking required for Dry Ice

- Class 9 DOT label
- DRY ICE UN 1845
- The amount of dry ice in the package in kilograms must be shown. One pound equals 2.2 kg.
- Dry ice must also be listed on the "Shippers Declaration For Dangerous Goods"





These shippers are also available for use in the State Courier system and USPS



Shipper for mycobacteriology specimen



Enteric Shipper, contains Cary-Blair transport medium



Shipper for parasitology stool sample

Bioterrorism Specimens and Cultures

Prior notification is requested for specimens and/or cultures being sent for "rule out/rule in" testing for bioterrorism agents.

Please notify **Dr. Jennifer Meredith**, **803-896-0870**, before shipping these diagnostic specimens or cultures.

Alternate: Dr. Arthur Wozniak 803-896-0965

The shipping address for Bureau of Laboratories is:

Bureau of Laboratories Business hours are 8:00 AM to 4:30 PM

8231 Parklane Road Monday through Friday, except for state holidays

Columbia, SC 29223

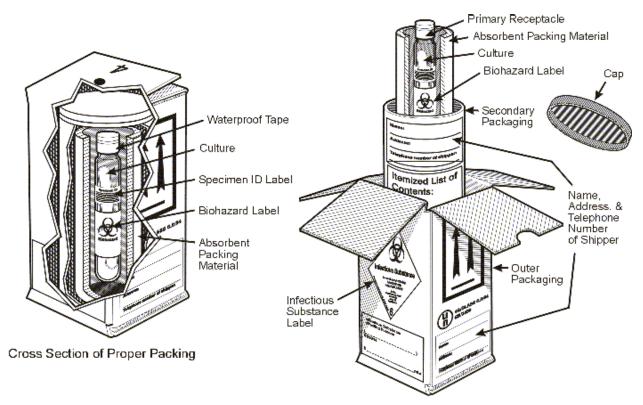
24/7 telephone number 803-896-0800

For questions on shipping information, contact:

Connie Gray, Safety Officer SC DHEC Bureau of Laboratories 803-896-0956 FAX 803-896-0983

Important Points to Remember

- The shipper is responsible for the infectious substance package until it is in the hands of the recipient. **Proper packaging, marking and labeling is the shipper's responsibility.**
- Commercial carriers (Federal Express, Airborne Express, etc.) may have additional requirements which are unique to their company. If you have any questions on packaging, marking, labeling, or documentation, always check with the commercial carrier you plan to use.
- Make sure that the correct marking and labeling information is on the outside packaging.
- Do not put laboratory forms inside the secondary container with the specimen.
- The outside packaging should have the name and telephone number of a person who is knowledgeable about the contents of the shipment. This is important emergency information in the event an exposure occurs during shipping.
- Do NOT put biohazard labels on the outside packaging. The biohazard label should be on the secondary receptacle.
- Do NOT use excessive tape to close the outside container. One piece of clear packaging tape should be adequate.
- Do NOT cover or deface any label or marking. A commercial transporter will not accept the package.
- Seal the package with clear shipping tape. Cut the tape to open the package. Pulling the tape off often defaces the markings and labels on the outside packaging.
- If an overpack with dry ice is used, a good rule of thumb is to add at least 6 pounds per 24-hour period. The US Postal Service limits the amount of dry ice per package to 5 pounds; therefore if more than 5 pounds of dry ice is needed, another transporter must be used.
- Employees shipping infectious substances must be trained on proper packaging and labeling. Training must be documented. Retraining is required when the regulations change or every three years. Some transporters will require a written certification of the training.
- If the infectious material is sent through the United States Postal Service, the package must be sent by Priority Mail or First Class Mail, using Registered Service.



Packing and Labeling of Infectious Substances Category A

Transporting Infectious Substances in a private or DHEC vehicle

Secure the properly packed and labeled infectious substance package in the vehicle as far away as possible from the driver, preferably in the trunk if available. If the vehicle is involved in an accident, the package should not be thrown around the vehicle. If there is an accident, emergency responders need to know that infectious substances are in the package.

References for information in this document:

IATA Dangerous Goods Regulations, 47th edition, effective January 1, 2006 to December 31, 2006

United States Postal Service, Domestic Mail Manual

Centers for Disease Control and Prevention, Guidelines for the Shipment of Dried Blood Spot Specimens.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to FedEx Express)

Shipper Air Waybill No SC DHEC Bureau of Laboratories 8231 Parklane Road Page 1 of 1 Pages Columbia, SC 29223 Shipper's Reference Number Responsibel party Connie Gray or Dr. Arthur Wozniak 1-803-896-0800 Consignee CDC 1234 Clifton Road Atlanta, GA Two completed and signed copies of this Declaration must be handed to the operator. WARNING Failure to comply in all respects with the applicable TRANSPORT DETAILS Dangerous Goods Regulations may be in breach This shipment is within the Airport of Departure of the applicable law, subject to legal penalties. limitations prescribed for This Declaration must not, in any circumstances, Columbia, SC (delete non-applicable) be completed and/or signed by a consolidator, a PASSENGER AND CARGO AIRCRAFT forwarder or an IATA cargo agent. CARGO AIRGEAFT ONLY Airport of Destination Shipment type: (delete non-applicable)
NON-RADIOACTIVE Atlanta, GA

NATURE AND QUANTITY OF DANGEROUS	COODE

Dangerous G	oods ld	entification					
Proper Shipping Name	Class or Divi- sion	UN or ID No.	Pack- ing Group	Subsi- diary Risk	Quantity and Type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Hepatitis B virus culture)	6. 2	UN2814			50 mls packed in one Fibreboard Box	602	

Additional Handling Information

I declare that all of the applicable air transport requirements have been met.

Emergency Telephone Number 803-896-0800

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked, and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory Carlton Atkinson, Material Logistics Manager Place and Date Columbia, SC 9-15-03 Signature

(see warning above) Couldon Atkinson

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to FedEx Express)

Shipper

SC DHEC Bureau of Laboratories 8231 Parklane Road

Columbia, SC 29223

Responsibel party Connie Gray or Dr. Arthur Wozniak 1-803-896-0800

Air Waybill No

Page 1 of 1 Pages

Shipper's Reference Number

Consignee

1234 Clifton Road

Atlanta, GA



Failure to comply in all respects with the applicable

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

TRANSPORT DETAILS

This shipment is within the limitations prescribed for (delete non-applicable)

Airport of Departure Columbia, SC Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

PASSENGER AND CARGO AIRCRAFT

Airport of Destination

Atlanta, GA

Shipment type: (delete non-applicable)
NON-RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification							
Proper Shipping Name	Class or Divi- sion	UN or ID No.	Pack- ing Group	Subsi- diary Risk	Quantity and Type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Hepatitis B virus culture)	6. 2	UN2814			50 mls packed in one Fibreboard Box	602	
Dry Ice	9	UN1845	Ш		3 kg Overpack used	904	

Additional Handling Information

I declare that all of the applicable air transport requirements have been met.

Emergency Telephone Number 803-896-0800

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked, and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory Carlton Atkinson, Material Logistics Manager

Place and Date Columbia, SC 9-15-03

Signature

(see warning above) Carbon Atkinson

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT

FEE POLICY

The Bureau of Laboratories is only partially supported by legislative appropriations from State Funds. Therefore, we have been authorized to charge fees under certain conditions.

1. TEST FEES:

A fee is charged for those tests which benefit only the individual patient or which are readily available from private sources. A list of current billable tests and charges follows.

No fee is charged for tests considered Public Health Testing. These are paid for by tax monies.

Exempt from charges:

- A. Tests that are not reasonably available from qualified private laboratories
- B. Tests whose result is primarily of epidemiologic or public health significance.
- C. Tests run as a matter of bureau policy which are not requested by the physician.
- D. When the patient is medically indigent.
 In this case, the physician will be billed, but may deduct the charges before remitting. See billing procedures.
- E. Repeat tests for Newborn Screening.

 If the repeat test was requested by the Bureau of Laboratories, i.e., initial test was invalid due to early dismissal, or improperly collected specimen or insufficient quantity or other reason, there is no charge for the repeat test.

 All other second or repeat tests are subject to the full fee.

2. RETRIEVAL OF RECORDS:

When minimal time (less than 15 minutes) is required to retrieve and copy requests for laboratory documents or records, no charge will be levied.

Requests for laboratory documents or records requiring more than 15 minutes retrieval and copy time, will be assessed a charge of \$20.00/ hour.

BILLING PROCEDURE

Bills are generated monthly and provide a line listing of patients and tests..

Bills are generated by Sender and/or Billing number. These can be obtained by calling 896-0810.

Do not send payment with the specimen. PAY ONLY WHEN YOU RECEIVE A BILL. Please do not send cash payments.

The bill will consist of two copies: The blue and white "remittance" copy must be returned with your payment for proper crediting of your account. The yellow "provider" copy should be retained for your records.

On the left side of the bill there is a column headed "Eligible for NON payment." In this column, please place a "X" beside the name of any patient listed who is considered to be unable to pay for the test, ie indigent. Place the total charges for patients eligible for non-payment in the indicated space at the upper right-hand corner of the bill and deduct this amount from the total charges. Please indicate the amount remitted.

Billing is done through the DHEC Bureau of Finance, not the Laboratory If an error is found on the bill, please write comments on the face of the bill or an attached sheet of paper and the problem will be corrected. You may also contact the DHEC Receivable Bureau of Finance at 898-3450 or the Bureau of Laboratories at 896-0942.

Delinquent accounts are subject to having test results withheld until the account is paid in full.

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